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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2020–0519; Special Conditions No. 25–773–SC]

Special Conditions: Aerospace Design and Compliance, LLC, Bombardier, Inc. Model CL–600–2B19 Airplane; Installation of a Therapeutic Oxygen System for Medical Use

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Bombardier Inc. (Bombardier) Model CL–600–2B19 airplane. This airplane, as modified by Aerospace Design and Compliance, LLC (Aerospace Design and Compliance), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The design feature is an installation of a therapeutic oxygen system for medical use. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Hettman, Propulsion & Mechanical Systems, AIR–672, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3171; email *Robert.Hettman@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On November 20, 2019, Aerospace Design and Compliance applied for a supplemental type certificate for the installation of a therapeutic oxygen system for medical use in the executive interiors of the Bombardier Model CL–600–2B19 airplane. The Model CL–600–2B19 airplane, which is currently approved under Type Certificate No. A21EA, is a twin-engine transport airplane with a maximum takeoff weight of 47,450 lbs. The Model CL–600–2B19 airplane will have 55 seats approved for taxi, takeoff, and landing.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Aerospace Design and Compliance must show that the Bombardier Model CL–600–2B19 airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A21EA, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Bombardier Model CL–600–2B19 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Bombardier Model CL–600–2B19 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Bombardier Model CL–600–2B19 airplane will incorporate the following novel or unusual design features:

A therapeutic oxygen system for medical use.

As a part of the executive interior installation, the gaseous passenger-oxygen system will be outfitted with a therapeutic oxygen system. The therapeutic oxygen system shares the same supply of oxygen with the existing passenger oxygen system and consists of multiple constant-flow oxygen outlets located throughout the cabin. The flightcrew can turn the therapeutic oxygen system on and off from the flightdeck to allow use at any point during the flight, and to preserve a sufficient remaining oxygen reserve, in the event therapeutic oxygen is used for medical purposes, to accommodate the passengers in the event of an emergency oxygen situation.

Discussion

No specific regulations address the design and installation of required passenger oxygen systems that share a supply source with an optional oxygen system used specifically for therapeutic applications. Therapeutic oxygen systems have been previously certified, and were generally considered an extension of the passenger oxygen system for the purpose of defining the applicable regulations. As a result, existing requirements, such as §§ 25.1309, 25.1441(b) and (c), 25.1451, and 25.1453, in the Bombardier Model CL–600–2B19 airplanes' certification basis applicable to this STC project, provide some design standards appropriate for oxygen system installations. In addition, § 25.1445 includes standards for oxygen distribution systems when oxygen is supplied to flightcrew and passengers. If a common source of supply is used, § 25.1445(a)(2) requires a means to separately reserve the minimum supply required by the flightcrew.

Section 25.1445 is intended to protect the flightcrew by ensuring that an adequate supply of oxygen is available to complete a descent and landing following a loss of cabin pressure. When the regulation was written, the only passenger oxygen system designs were supplemental oxygen systems intended to protect passengers from hypoxia in the event of a decompression. Existing

passenger oxygen systems did not include design features that would allow the flightcrew to control oxygen to passengers during flight. There are no similar requirements in § 25.1445 when oxygen is supplied from the same source to passengers for use during a decompression, and for discretionary or first-aid use any time during the flight. In the design, the passenger and therapeutic oxygen systems use the same source of oxygen. These special conditions contain additional design requirements for the equipment involved in this dual therapeutic oxygen plus gaseous oxygen installation.

Furthermore, the potential hazard that can exist when the oxygen content of an enclosed area becomes too high because of system leaks, malfunction, or damage from external sources, make it necessary to ensure that adequate safety standards are applied to the design and installation of the oxygen system in Bombardier Model CL–600–2B19 airplanes. These potential hazards also necessitate development and application of appropriate additional design and installation standards.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Discussion of Comments

The FAA issued Notice of Proposed Special Conditions No. 25–20–06–SC for the Bombardier Model CL–600–2B19 airplane, which was published in the **Federal Register** on June 16, 2020 (85 FR 36351). No substantive comments were received, and the special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions are applicable to the Bombardier Model CL–600–2B19 airplane. Should Aerospace Design and Compliance apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A21EA to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**. However, as the certification date for the Bombardier Model CL–600–2B19 airplane is imminent, the FAA finds that good cause exists to make these special conditions effective upon publication.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Bombardier Model CL–600–2B19 airplanes, as modified by Aerospace Design and Compliance, LLC.

The distribution system for the passenger therapeutic oxygen systems must be designed and installed to meet requirements as follows:

1. When oxygen is supplied to passengers for both supplemental and therapeutic purposes, the distribution system must be designed for either—

a. A source of supplemental oxygen for protection following a loss of cabin pressure, and a separate source for therapeutic purposes: Or

b. A common source of supply with means to separately reserve the minimum supply required by the passengers for supplemental use following a loss of cabin pressure.

Issued in Des Moines, Washington, on July 22, 2020.

James E. Wilborn,

Acting Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2020–16280 Filed 8–11–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. FAA–2020–0756; Special Conditions No. 29–050–SC]

Special Conditions: Leonardo S.p.A. (Leonardo) Model AW189, Search and Rescue (SAR) Automatic Flight Control System (AFCS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Leonardo Model AW189 helicopters. This model of helicopter, as modified by Leonardo, will have the novel or unusual design feature associated with installing an optional SAR AFCS. The applicable airworthiness standards do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to show a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is August 27, 2020. The FAA must receive your comments by September 11, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0756 using any of the following methods:

☐ *Federal eRegulations Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.

☐ *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

☐ *Hand Delivery of Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

☐ *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://regulations.gov,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington,

DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

FAA, Mr. Mitchell Soth (AIR–713), Regulations and Policy Section, AIR–681, Rotorcraft Standards Branch, Policy & Innovation Division, Aircraft Certification Service, 10101 Hillwood Parkway, Fort Worth, Texas 76177; telephone (817) 222–5104; facsimile (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Reason for No Prior Notice and Comment Before Adoption

The FAA has determined, in accordance with 5 U.S. Code 553(b)(3)(B) and 553(d)(3), that notice and opportunity for prior public comment hereon are unnecessary because substantially identical special conditions have been previously subject to the public comment process in several prior instances such that the FAA is satisfied that new comments are unlikely. For the same reason, the FAA finds that good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment.

Special conditions No.	Company and helicopter model
No. 29–041–SC [1] ..	Bell Helicopter Textron Inc. Model 412EP Helicopter.
No. 29–022–SC [2] ..	Eurocopter France Model EC225LP Helicopter.
No. 29–027–SC [3] ..	Agusta S.p.A. Model AW139 and AB139 Helicopter.
No. 29–023–SC [4] ..	Sikorsky Aircraft Corporation Model S–92A Helicopter.

[1] 82 FR 24458, May 30, 2017.
[2] 77 FR 60883, October 5, 2012.
[3] 77 FR 44110, July 27, 2012.
[4] 75 FR 77524, December 13, 2010.

Comments Invited

While the FAA did not precede these special conditions with a notice of proposed special conditions, the FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed late if it is possible to do so without incurring expense or delay. The FAA may change these special conditions based on the comments received.

Background

On October 18, 2019, Leonardo applied for a change to Type Certificate (TC) No. R00004RD to install an optional SAR AFCS in the Model AW189 helicopter. The Model AW189 is a transport category helicopter certificated for Category A operations. This helicopter is also certificated for instrument flight under the requirements of Appendix B of 14 CFR part 29, Amendment 29–51. It is powered by two General Electric CT7–2E1 engines and is capable of carrying a maximum of 19 passengers and 2 crew members.

Leonardo proposes that the Model AW189 include the use of a novel and unusual design feature, which is a SAR AFCS. The use of dedicated AFCS upper modes, in which a fully coupled autopilot provides operational SAR profiles, is needed for SAR operations conducted over water in offshore areas clear of obstructions. The SAR modes enable the helicopter pilot to fly fully coupled maneuvers, to include predefined search patterns during cruise flight, and to transition from cruise flight to a stabilized hover and departure (transition from hover to cruise flight). The SAR AFCS also includes an auxiliary crew control that allows another crewmember (such as a hoist operator) to have limited authority to control the helicopter's longitudinal and lateral position during hover operations.

Flight operations conducted over water at night may have an extremely limited visual horizon with little visual reference to the surface even when conducted under Visual Meteorological Conditions. Consequently, the certification requirements for SAR modes must meet Appendix B to 14 CFR part 29. While Appendix B to 14 CFR part 29 prescribes airworthiness criteria for instrument flight, it does not consider operations below instrument flight minimum speed (V_{MINI}), whereas the SAR modes allow for coupled operations at low speed, all-azimuth flight to zero airspeed (hover).

The regulations as currently promulgated did not envision instrument flight below the Appendix B envelope, including hover using AFCS modes. This necessitates the development of a special condition to address the gap in 14 CFR part 29 regulations and the lack of adequate airworthiness standards for AFCS SAR mode certification to include flight characteristics, performance, and installed equipment and systems.

Type Certification Basis

Under 14 CFR 21.101, Leonardo must show the AW189 model helicopter, as changed, continues to meet either the applicable provisions of the regulations incorporated by reference in TC No. R00004RD or the applicable regulations in effect on the date of application for the change, depending on the significance of the change as defined by 14 CFR 21.101. The regulations incorporated by reference in the TC are commonly referred to as the ''original type certification basis.'' The regulations incorporated by reference in R00004RD are as follows: 14 CFR 21.29 and Part 29, Amendments 29–1 through 29–52 (dated March 30, 2010). 14 CFR 36, Appendix H, Amendment 36–1 through Amendment 36–29 (dated March 11, 2013). Special Condition No. 29–034–SC, 30 Minute All Engines Operating (AEO) Power Rating: 14 CFR 29.1049, 29.1305, 29.1521.

Equivalent Level of Safety Findings (ELOS) issued against:

(a) 14 CFR 29.807(c) Passenger emergency exits (documented in ELOS Memo TC4265RD–R–C–01).

(b) 14 CFR 29.813(c) Passenger access to each emergency exit (documented in ELOS Memo TC4265RD–R–C–02).

(c) 14 CFR 29.807 (d)(2) & (d)(3) Ditching emergency exits for passengers (documented in ELOS Memo TC4265RD–R–C–04).

(d) 14 CFR 29.815 Main aisle width (documented in ELOS Memo TC4265RD–R–C–05).

(e) 14 CFR 29.1545(b) Airspeed indicator (documented in ELOS Memo TC4265RD–R–F–01).

(f) 14 CFR 29.1305 and § 29.1549 Power Index (documented in ELOS Memo TC4265RD–R–F–03).

Regulatory Basis for Special Conditions

The Administrator has determined that the applicable airworthiness regulations (that is, 14 CFR part 29) do not contain adequate or appropriate safety standards for the Leonardo Model AW189 helicopter because of a novel or unusual design feature. Therefore, special conditions are prescribed under the provisions of 14 CFR 21.16.

The FAA issues special conditions, as defined in § 11.19, under § 11.38, and they become part of the type certification basis under § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should the TC for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same TC be modified to incorporate the

same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

Novel or Unusual Design Features

The Leonardo Model AW189 helicopters will incorporate the following novel or unusual design features:

The SAR system is composed of a navigation computer with SAR modes, an AFCS that provides coupled SAR functions, hoist operator control, a hover speed reference system, and two radio altimeters. The AFCS coupled SAR functions include:

(a) Hover hold at selected height above the surface.

(b) Ground speed hold.

(c) Transition down and hover to a waypoint under guidance from the navigation computer.

(d) SAR pattern, transition down, and hover near a target over which the helicopter has flown.

(e) Transition up, climb, and capture a cruise height.

(f) Capture and track SAR search patterns generated by the navigation computer.

(g) Monitor the preselected hover height with an automatic increase in collective if the aircraft height drops below the safe minimum height.

These SAR modes are intended to be used over large bodies of water in areas clear of obstructions. Further, the use of the modes that transition down from cruise to hover will include operation at airspeeds below V_{MINI}.

The SAR system only entails navigation, flight control, and coupled AFCS operation of the helicopter. The system does not include the additional equipment that may be required for over water flight or external loads to meet other operational requirements.

Discussion

The following is a summary of the final special conditions:

(a) In addition to the requirements of 14 CFR part 29 for Category A and Appendix B Helicopter Instrument Flight (IFR), the SAR Helicopter and AFCS must:

(1) Be safe and controllable in flight for all three axes at airspeeds from V_{MINI} to hover,

(2) have adequate dynamic stability, and

(3) provide an automatic transition sequencing from the approved Appendix B IFR envelope without unintended flight below a safe minimum height and return to the Appendix B envelope.

(4) Deliver adequate one engine inoperative (OEI) performance.

(5) Operate safely in the requested flight envelope, which includes:

(i) Sea States where the wave height is 2.5m (8.2 feet) and

(ii) a headwind of 25 knots, 17 knots from all other azimuths.

(6) Contain relevant limitations and procedures, including operations in salt spray environments.

(b) The design and system architecture of the SAR helicopter must:

(1) Include a ground mapping radar.

(2) Incorporate a system to limit engine power demand such that engine limits are not exceeded.

(3) Provide the following to each pilot:

(i) A selectable Go-Around Mode and minimum safe height,

(ii) aircraft height above the surface,

(iii) heading and pilot-selected heading information,

(iv) aircraft and pilot selected ground speeds when used by the AFCS, and

(v) wind speed and direction.

(4) Include a system that monitors flight guidance deviations, failures, mode changes and alerts the flight crew.

(5) Provide to the SAR Hoist operator a control which includes a flight control with limited authority, which

(i) is designed, located and safely controllable for that operator without interfering with the safe operation of the helicopter, and

(ii) can be safely overridden by the pilot or copilot.

(6) Ensure the AFCS design is reliable in relation to the effects of its failures and operating environment.

Applicability

These special conditions apply to the Leonardo Model AW189 helicopter. Should Leonardo apply at a later date for an amendment to the TC to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Leonardo Model AW189 helicopter. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 29

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Leonardo Model AW189 helicopter when the optional Search and Rescue (SAR) Automatic Flight Control System (AFCS) is installed:

In addition to the part 29 certification requirements for Category A and helicopter instrument flight for Appendix B, the following additional requirements must be met for certification of the SAR AFCS:

(a) *SAR Flight Modes.* The coupled SAR flight modes must provide:

(1) Safe and controlled flight in the three axes at all airspeeds (lateral position and speed, longitudinal position and speed, and height and vertical speed) from the previous V_{MINI} to a hover (within the maximum demonstrated wind envelope).

(2) Automatic transition to the helicopter instrument flight (Appendix B) envelope as part of the normal SAR mode sequencing.

(3) A pilot-selectable Go-Around mode that safely interrupts any other coupled mode and automatically transitions the helicopter to the instrument flight (Appendix B) envelope.

(4) A means to prevent unintended flight below a safe minimum height. Pilot-commanded descent below the safe minimum height is acceptable, provided the alerting requirements in paragraph (b)(8)(i) of these Special Conditions alert the pilot of this descent below safe minimum height.

(b) *SAR Mode System Architecture.* To support the integrity of the SAR modes, the following system architecture is required:

(1) Ground mapping radar function that presents real-time information to the pilots.

(2) A system for limiting the engine power demanded by the AFCS when any of the automatic piloting modes are engaged, so full authority digital engine control power limitations, such as torque and temperature, are not exceeded.

(3) A system providing the aircraft height above the surface and final pilot-selected height at a location on the instrument panel in a position acceptable to the FAA that will make it plainly visible to and usable by any pilot at their station.

(4) A system providing the aircraft heading and the pilot-selected heading at a location on the instrument panel in a position acceptable to the FAA that will make it plainly visible to and usable by any pilot at their station.

(5) A system providing the aircraft longitudinal and lateral ground speeds and the pilot-selected longitudinal and

lateral ground speeds when used by the AFCS in the flight envelope where airspeed indications become unreliable. This information must be presented at a location on the instrument panel in a position acceptable to the FAA that is plainly visible to and usable by any pilot at their station.

(6) A system providing wind speed and wind direction when automatic piloting modes are engaged or transitioning from one mode to another.

(7) A system that monitors for flight guidance deviations and failures and contains an alerting function that provides the flight crew with enough information to take appropriate corrective action.

(8) The alerting system must provide visual or aural alerts, or both, to the flight crew under any of the below conditions:

(i) When the stored or pilot-selected safe minimum height is reached.

(ii) When a SAR mode system malfunction occurs.

(iii) When the AFCS changes modes automatically from one SAR mode to another. For normal transitions from one SAR mode to another, a single visual or aural alert may suffice. For a SAR mode malfunction or a mode having a time-critical component, the flight crew alerting system must activate early enough to allow the flight crew to take timely and appropriate action. The alerting system means must be designed to alert the flight crew in order to minimize crew errors that could create an additional hazard.

(9) The SAR system hoist operator control is considered a flight control with limited authority and must comply with the following:

(i) The hoist operator control must be designed and located to provide for convenient operation and to prevent confusion and inadvertent operation.

(ii) The helicopter must be safely controllable by the hoist operator control throughout the range of that control.

(iii) The hoist operator control may not interfere with the safe operation of the helicopter.

(iv) Pilot and copilot flight controls must be able to smoothly override the limited control authority of the hoist operator control, without exceptional piloting skill, alertness, or strength, and without the danger of exceeding any other limitation because of the override.

(10) The reliability of the AFCS must be related to the effects of its failure. The occurrence of any failure condition that would prevent continued safe flight and landing must be extremely improbable. For any failure condition of the AFCS which is not shown to be extremely improbable:

(i) The helicopter must be safely controllable and capable of continued safe flight without exceptional piloting skill, alertness, or strength. Additional unrelated probable failures affecting the control system must be evaluated.

(ii) The AFCS must be designed so that it cannot create a hazardous deviation in the flight path or produce hazardous loads on the helicopter during normal operation or in the event of a malfunction or failure, assuming corrective action begins within an appropriate period of time. Where multiple systems are installed, subsequent malfunction conditions must be evaluated in sequence unless their occurrence is shown to be improbable.

(11) A functional hazard assessment and a system safety assessment must address the failure conditions associated with SAR operations.

(i) For SAR catastrophic failure conditions, changes may be required to the following:

(A) System architecture.

(B) Software and complex electronic hardware design assurance levels.

(C) High Intensity Radiated Fields (HIRF) test levels.

(D) Instructions for continued airworthiness.

(ii) The assessments must consider all the systems required for SAR operations to include the AFCS, all associated AFCS sensors (for example, radio altimeter), and primary flight displays. Electrical and electronic systems with SAR catastrophic failure conditions (for example, AFCS) must comply with the § 29.1317(a)(4) HIRF requirements.

(c) *SAR Mode Performance Requirements.*

(1) Demonstrate the SAR modes for the requested flight envelope, including the following minimum sea-state and wind conditions:

(i) *Sea State:* Wave height of 2.5 meters (8.2 feet), considering both short and long swells.

(ii) *Wind:* 25 knots headwind; 17 knots for all other azimuths.

(2) The selected hover height and hover velocity must be captured (to include the transition from one captured mode to another captured mode) accurately and smoothly and not exhibit any significant overshoot or oscillation.

(3) The minimum use height (MUH) for the SAR modes must be no more than the maximum loss of height following any single failure or any combination of failures not shown to be extremely improbable, plus an additional margin of 15 feet above the surface. MUH is the minimum height at which any SAR AFCS mode may be engaged.

(4) The SAR mode system must be usable up to the maximum certified gross weight of the aircraft or to the lower of the following weights:

(i) Maximum emergency flotation weight.

(ii) Maximum hover Out-of-Ground Effect (OGE) weight.

(iii) Maximum demonstrated weight.

(d) *Flight Characteristics.*

(1) The basic aircraft must meet all of the part 29 airworthiness criteria for helicopter instrument flight (Appendix B).

(2) For SAR mode coupled flight below V_{MINI}, at the maximum demonstrated winds, the helicopter must be able to maintain any required flight condition and make a smooth transition from any flight condition to any other flight condition without requiring exceptional piloting skill, alertness, or strength, and without exceeding the limit load factor. This requirement also includes aircraft control through the hoist operator's control.

(3) For coupled flight below the previously established V_{MINI}, the following stability requirements replace the stability requirements of paragraph IV, V, and VI of Appendix B to part 29:

(i) *Static Longitudinal Stability:* The requirements of paragraph IV of Appendix B are not applicable.

(ii) *Static Lateral-Directional Stability:* The requirements of paragraph V of Appendix B are not applicable.

(iii) *Dynamic Stability:* The requirements of paragraph VI of Appendix B are replaced with the following two paragraphs:

(A) Any oscillation must be damped and any aperiodic response must not double in amplitude in less than 10 seconds. This requirement must also be met with degraded upper mode(s) of the AFCS. An ''upper mode'' is a mode that utilizes a fully coupled autopilot to provide an operational SAR profile.

(B) After any upset, the AFCS must return the aircraft to the last commanded position within 10 seconds or less.

(4) With any of the upper modes of the AFCS engaged, the pilot must be able to manually recover the aircraft and transition to the normal (Appendix B) IFR flight profile envelope without exceptional skill, alertness, or strength.

(e) *One-Engine Inoperative (OEI) Performance Information.*

(1) The following performance information must be provided in the Rotorcraft Flight Manual Supplement (RFMS):

(i) OEI performance information and emergency procedures, providing the

maximum weight that will provide a minimum clearance of 15 feet above the surface, following failure of the critical engine in a hover. The maximum weight must be presented as a function of the hover height for the temperature and pressure altitude range requested for certification. The effects of wind must be reflected in the hover performance information.

(ii) Hover OGE performance with the critical engine inoperative for OEI continuous and time-limited power ratings for those weights, altitudes, and temperatures for which certification is requested.

Note: These OEI performance requirements do not replace performance requirements that may be needed to comply with the airworthiness or operational standards (14 CFR 29.865 or 14 CFR part 133) for external loads or human external cargo.

(f) *RFMS.*

(1) Limitations necessary for safe operation of the SAR system to include:

(i) Minimum crew requirements. No fewer than two pilots, except for approved external load operations that will also require a hoist operator.

(ii) Maximum SAR weight as determined by the lower of the SAR Mode performance requirement of paragraph (c)(4) of these Special Conditions or the aircraft performance information provided by paragraph (e) of these Special Conditions.

(iii) Maximum demonstrated sea state conditions for ditching compliance.

(iv) Engagement criteria for each of the SAR modes to include MUH (as determined in subparagraph (c)(3)) of these Special Conditions.

(v) Normal and emergency procedures for operation of the SAR system (including operation of the hoist operator control), with AFCS failure modes, AFCS degraded modes, and engine failures.

(2) Performance information:

(i) OEI performance and height-loss.

(ii) Hover OGE performance information, utilizing OEI continuous and time-limited power ratings.

(iii) The maximum wind envelope demonstrated in flight test.

(iv) Information and advisory information concerning operations in a heavy salt spray environment, including any airframe or power effects as a result of salt encrustation.

(g) *Flight Demonstration.*

(1) Before approval of the SAR system, an acceptable flight demonstration of all the coupled SAR modes is required.

(2) The AFCS must provide fail-safe operations during coupled maneuvers. The demonstration of fail-safe operations must include a pilot workload assessment associated with manually flying the aircraft to an altitude greater than 200 feet above the surface and an airspeed of at least the best rate of climb airspeed (V_y).

(3) For any failure condition of the SAR system not shown to be extremely improbable, the pilot must be able to make a smooth transition from one flight mode to another without exceptional piloting skill, alertness, or strength.

(4) Failure conditions that are not shown to be extremely improbable must be demonstrated by analysis, ground testing, or flight testing. For failures demonstrated in flight, the following normal pilot recovery times are acceptable:

(i) *Transition modes (Cruise-to-Hover/Hover-to-Cruise) and Hover modes:* Normal pilot recognition plus 1 second.

(ii) *Cruise modes:* Normal pilot recognition plus 3 seconds.

(5) All AFCS malfunctions must include evaluation at the low-speed and high-power flight conditions typical of SAR operations. Additionally, AFCS hard-over, slow-over, and oscillatory malfunctions, particularly in yaw, require evaluation. AFCS malfunction testing must include a single or a combination of failures (such as, erroneous data from and loss of the radio altimeter, attitude, heading, and altitude sensors) that are not shown to be extremely improbable.

(6) The flight demonstration must include the following environmental conditions:

(i) Swell into the wind.

(ii) Swell and wind from different directions.

(iii) Cross swell.

(iv) Swell of different lengths (short and long swell).

(7) The flight demonstration must also evaluate OEI procedures from hover while hoisting an external load.

Issued in Fort Worth, Texas, on July 31, 2020.

Jorge Castillo,

Manager, Rotorcraft Standards Branch, AIR–680 Policy & Innovation Division, Aircraft Certification Service.

[FR Doc. 2020–17089 Filed 8–10–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2018–F–3347]

Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of chromium propionate.

DATES: This rule is effective August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–224), Rockville, MD 20855, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the regulations for food additives permitted in feed and drinking water of animals at 21 CFR 573.304 *Chromium Propionate* to more accurately reflect the approved conditions for the safe use of chromium propionate in horses.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 704). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to correct an inaccurate statement and is nonsubstantive.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 573.304 [Amended]

■ 2. In § 573.304, in paragraphs (d)(1) and (e)(1), remove the word ''complete''.

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–15826 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9896]

RIN 1545–BO53

Rules Regarding Certain Hybrid Arrangements; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final regulations Treasury Decision 9896 that were published in the **Federal Register** on Wednesday, April 8, 2020. The final regulations providing guidance regarding hybrid dividends and certain amounts paid or accrued pursuant to hybrid arrangements, which generally involve arrangements whereby U.S. and foreign tax law classify a transaction or entity differently for tax purposes.

DATES:

Effective date: This correction is effective on August 12, 2020.

Applicability dates: For dates of applicability, see §§ 1.267A–7 and 1.1503(d).

FOR FURTHER INFORMATION CONTACT: Tracy Villecco at (202) 317–6933 or Tianlin (Laura) Shi at (202) 317–6936 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9896) that are the subject of this correction are issued under sections 267A and 1503(d) of the Code.

Need for Correction

As published April 8, 2020 (85 FR 19802), the final regulation (TD 9896; FR Doc. 2020–05924) contained errors that need to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

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

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.267A–5 is amended by revising paragraph (a)(20)(ii) to read as follows:

§ 1.267A–5 Definitions and special rules.

(a) * * *

(20) * * *

(ii) *Party to a structured arrangement.* A party to a structured arrangement means a tax resident, a taxable branch, or an entity that participates in the structured arrangement. For purposes of this paragraph (a)(20)(ii), in the case of an entity, the entity's participation in a structured arrangement is imputed to its investors. However, a tax resident, a taxable branch or an entity (the *relevant party*) is considered to participate in the structured arrangement only if—

(A) The relevant party (or a related tax resident or taxable branch, determined under paragraph (a)(14) of this section by treating the relevant party as a specified party) could, based on all the facts and circumstances, reasonably be expected to be aware of the hybrid mismatch; and

(B) The relevant party or one or more of its investors (or a related tax resident or taxable branch, determined under paragraph (a)(14) of this section by treating the relevant party or an investor as a specified party) shares in the value of the tax benefit resulting from the hybrid mismatch.

* * * * *

■ **Par. 3.** Section 1.267A–7 is amended by revising paragraph (a) to read as follows:

§ 1.267A–7 Applicability dates.

(a) *General rule.* Except as provided in paragraph (b) of this section, §§ 1.267A–1 through 1.267A–6 apply to taxable years ending on or after December 20, 2018, provided that such taxable years begin after December 31, 2017. However, taxpayers may apply the regulations in §§ 1.267A–1 through 1.267A–6 in their entirety (including by taking into account paragraph (b) of this section) for taxable years beginning after December 31, 2017, and ending before December 20, 2018. In lieu of applying the regulations in §§ 1.267A–1 through 1.267A–6 (including paragraph (b) of this section), taxpayers may apply the provisions matching §§ 1.267A–1 through 1.267A–6 (including by taking into account the provision matching paragraph (b) of this section) from the Internal Revenue Bulletin (IRB) 2019–03 (*https://www.irs.gov/pub/irs-irbs/irb19-03.pdf*) in their entirety for all taxable years ending on or before April 8, 2020.

* * * * *

§ 1.1503(d)–7 [Amended]

■ **Par. 4.** Section 1.1503(d)–7(c)(6)(iii)(A) is amended by removing ''paragraphs'' and adding ''paragraph'' in its place.

Martin V. Franks,

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

[FR Doc. 2020–15842 Filed 8–11–20; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0232; FRL–10009–42]

Nitrapyrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of nitrapyrin in or on sugar beet molasses, sugar beet roots, sugar beet tops, rapeseed seed, and the vegetable, tuberous and corm, crop subgroup 1C. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 12, 2020. Objections and requests for hearings must be received on or before October 13, 2020 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0232, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March

31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0232 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0232, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 28, 2019 (84 FR 57685) (FRL–10001–11), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F8723) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues nitrapyrin in or on beet, sugar, roots at 0.30 parts per million (ppm); beet, sugar, molasses at 0.70 ppm; beet, sugar, tops at 0.70 ppm; canola, seed at 0.30 ppm; canola, meal at 0.80 ppm; potato, processed potato waste at 1.50 ppm; and vegetable, tuberous and corm, subgroup at 0.60 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than requested and in some cases is establishing tolerances for different commodities than requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for nitrapyrin including exposure resulting from the tolerances established by this action.

On August 27, 2019 EPA published in the **Federal Register** a final rule establishing tolerances for residues of nitrapyrin in or on several fruit and vegetable commodities. See 84 FR 44708 (FRL–9996–85). That document contains a summary of the toxicological profile, assumptions for dietary exposure assessment, cumulative risk, and the safety factor for children, which, except for the cancer classification of nitrapyrin, have not changed.

In the analysis supporting the August 27, 2019 rule, EPA had concluded that nitrapyrin was appropriately classified as ''suggestive evidence of carcinogenic potential'' (See the document ''*Nitrapyrin. Human Health Risk Assessment for New Uses in/on Vegetable, Bulb, Crop Group 3–07; Vegetable Leafy, Crop Group 4–16; Vegetable, Brassica, Head and Stem Crop Group 5–16; Fruit, Citrus, Crop Group 10–10; Fruit, Citrus, Group 10–10, Dried Pulp; Fruit, Citrus, Group 10–*

10, Oil; and Leaf Petiole Subgroup 22B'' dated July 16, 2019 in docket ID EPA–HQ–OPP–2018–0095). The toxicological endpoints table noted that the chronic RfD would be protective of any potential cancer risk. Since that time, EPA has reassessed the carcinogenic potential of nitrapyrin (May 8, 2018 document titled, ''Nitrapyrin: Sixth Report of the Cancer Assessment Review Committee''). Based on information submitted by the registrant, nitrapyrin is now classified as ''not likely to be carcinogenic to humans at doses that do not result in CAR activation as indicated by *Cyp2b10* expression.'' Quantification of cancer risk using a non-linear RfD approach adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to nitrapyrin; therefore, a separate cancer dietary exposure and risk assessment was not conducted.

A summary of the toxicological endpoints for nitrapyrin used for human risk assessment can be found in the document titled ''Nitrapyrin. Human Health Risk Assessment for New Uses in/on Canola, Tuberous and Corm Vegetables (Crop Subgroup 1C), Sugar Beets, and Sorghum'' dated May 1, 2020 in docket number EPA–HQ–OPP–2019–0232.

Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the August 27, 2019 **Federal Register** action can be found at *http://www.regulations.gov* in the documents titled, ''Nitrapyrin. Human Health Risk Assessment for New Uses in/on Vegetable, Bulb, Crop Group 3–07; Vegetable Leafy, Crop Group 4–16; Vegetable, Brassica, Head and Stem Crop Group 5–16; Fruit, Citrus, Crop Group 10–10; Fruit, Citrus, Group 10–10, Dried Pulp; Fruit, Citrus, Group 10–10, Oil; and Leaf Petiole Subgroup 22B'' dated July 16, 2019. The document can be found in docket ID EPA–HQ–OPP–2018–0095.

The Agency conducted a revised risk assessment to incorporate exposure to residues of nitrapyrin from use on canola, tuberous and corm vegetables (crop subgroup 1C), and sugar beets. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water, although the latter exposure is not impacted by the new uses. Acute dietary risks are below the Agency's level of concern: 10% of the aPAD for all infants less than one year old, the most highly exposed population subgroup. Chronic dietary risks are below the Agency's level of concern: 22% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. There are no residential uses for nitrapyrin, so there is no short- or intermediate-term residential exposure to aggregate with the chronic dietary exposures. Finally, as indicated previously in this document, EPA does not expect any cancer risk below doses that do not result in CAR activation as indicated by *Cyp2b10* expression. Because the chronic RfD is below those levels, precluding doses that would result in CAR activation, EPA does not expect any cancer risk from aggregate exposure to nitrapyrin.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to nitrapyrin residues.

More detailed information on the subject action to establish a tolerance in or on canola, tuberous and corm vegetables (crop subgroup 1C), and sugar beets can be found in the document titled, ''Nitrapyrin. Human Health Risk Assessment for New Uses in/on Canola, Tuberous and Corm Vegetables (Crop Subgroup 1C), Sugar Beets, and Sorghum,'' dated May 1, 2020 by going to *http://www.regulations.gov.* The referenced document is available in the docket EPA–HQ–OPP–2019–0232.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection) is available to enforce the tolerance expression. Seven analytical methods are available in Volume II of the Pesticide Analytical Manual (PAM II—Pesticide Reg. Sec. 180.350) for tolerance enforcement for nitrapyrin and/or for metabolite 6–CPA.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established any MRLs for residues of nitrapyrin.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance on ''rapeseed, seed'' rather than the requested tolerance on ''canola, seed'' to be consistent with the terminology the Agency uses for that commodity. Also, although the petitioner requested a separate tolerance for canola, meal, EPA has determined that the tolerance established for rapeseed, seed will adequately cover residues in canola, meal. Based on the highest average field trial (HAFT) value from canola seed raw agricultural commodity (RAC) field trials, including combined residues of nitrapyrin and 6–CPA (0.151 ppm), and utilizing the processing factor (1.5X), the expected residues in meal are lower than the tolerance on rapeseed, seed. Therefore, the separate tolerance on canola meal is unnecessary.

Similarly, although the petitioner requested a tolerance on potato, processed potato waste at 1.50 ppm, EPA has determined that the tolerance established for tuberous and corm vegetables, subgroup 1C will adequately cover residues in processed potato waste. Based on HAFT (0.309 ppm) value from potato RAC and the median processing factor in potato processed commodities (1.0x), the expected residues in processed potato waste are lower than the tolerance for subgroup 1C. Therefore, the tolerance for potato, potato processed waste is not needed.

For beet, sugar, molasses, EPA calculated tolerance value based on the HAFT value from sugar beet root RAC for combined residues of nitrapyrin and 6–CPA (0.123 ppm) and the processing factor (2.9X); the result is expected residues lower than the tolerance requested for sugar beet roots. Therefore, the tolerance is being established at 0.5 ppm rather than as requested at 0.70 ppm.

Lastly, several of the tolerance values have been corrected to be consistent with the Agency's rounding class practice.

V. Conclusion

Therefore, tolerances are established for residues of nitrapyrin in or on beet, sugar, molasses at 0.5 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 0.7 ppm; rapeseed, seed at 0.3 ppm; and vegetable, tuberous and corm, crop subgroup 1C at 0.6 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 2, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.350, amend paragraph (a) by adding to the table, in alphabetical order, the commodities, ''Beet, sugar, molasses'', ''Beet, sugar, roots'', ''Beet, sugar, tops'', ''Rapeseed, seed'', and ''Vegetable, tuberous and corm, crop subgroup 1C'' to read as follows:

§ 180.350 Nitrapyrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, molasses	0.5
Beet, sugar, roots	0.3
Beet, sugar, tops	0.7
* * * * *	
Rapeseed, seed	0.3
* * * * *	
Vegetable, tuberous and corm, crop subgroup 1C	0.6
* * * * *	

* * * * *

[FR Doc. 2020–16456 Filed 8–11–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0510; FRL–10008–94]

Pethoxamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pethoxamid in or on multiple commodities which are identified and discussed later in this document. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 12, 2020. Objections and requests for hearings must be received on or before October 13, 2020 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0510, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the

current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0510 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0510, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8572) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pethoxamid in or on corn, field, forage at 0.015 parts per million (ppm); corn, field, stover at 0.02 ppm; corn, field, grain at 0.01 ppm; popcorn, stover at 0.01 ppm; popcorn, grain at 0.01 ppm; corn, sweet, forage at 0.50 ppm; corn, sweet, stover at 0.60 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; cotton, undelinted seed at 0.01 ppm; cotton, gin byproducts at 0.09 ppm; soybean, forage at 3.0 ppm; soybean, hay at 4.5 ppm; and soybean, seed at 0.01 ppm.

In the **Federal Register** of October 28, 2019 (84 FR 57685) (FRL–10001–11), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8572) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pethoxamid in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, forage at 0.015 ppm; corn, field, stover at 0.02 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.60 ppm; cotton, gin byproducts at 0.09 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; popcorn, grain at 0.01 ppm; popcorn, stover at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; soybean, forage at 3.0 ppm; soybean, hay at 4.5 ppm; and soybean, seed at 0.01 ppm. The October 28, 2019 Notice of Filing (NOF) supersedes the April 11, 2018 NOF. The documents referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.*

Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what was requested. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in

FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pethoxamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pethoxamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The hazard database for pethoxamid indicates that the primary effects occur in the liver and thyroid, including increased changes in thyroid weight, thyroid hypertrophy, thyroid hyperplasia, thyroid follicular cell adenomas, and benign hepatocellular adenomas in mice. Potential signs of neurotoxicity occurring at very high doses were considered agonal, rather than adverse. Reproductive toxicity was not observed, and developmental/offspring toxicity was limited to decreased fetal body weights and late abortions. Specific information on the studies received and the nature of the adverse effects caused by pethoxamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled, ''*Pethoxamid: Human Health Risk Assessment for Proposed Section 3 Registration of the New Active Ingredient on Corn, Cotton, and Soybeans and in/on Turf and Ornamental Sites*'' (hereinafter ''Pethoxamid Human Health Risk Assessment'') on pages 43–52 in docket ID number EPA–HQ–OPP–2017–0510.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for permethrin used for human risk assessment can be found in the Pethoxamid Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pethoxamid, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pethoxamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for pethoxamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used 2003–2008 food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the chronic analysis assumed tolerance-level residues, default processing factors and 100 percent crop treated (PCT) estimates.

iii. *Cancer.* Based on the Agency's analysis of the available data, EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pethoxamid. Quantification of cancer risk using a non-linear RfD approach will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to pethoxamid; therefore, a separate cancer dietary assessment was not conducted.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for pethoxamid. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pethoxamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pethoxamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Using the Pesticides in Water Calculator (PWC) and Pesticide Root Zone Model and the Varying Volume Water Model (PRZM/VVWM) models, EPA calculated the estimated drinking water concentrations (EDWCs) of pethoxamid for chronic exposures in surface and ground water. EPA used the modeled EDWCs directly in the dietary exposure model to account for the contribution of pethoxamid residues in drinking water as follows: 7.45 ppb was used in the chronic assessment.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pethoxamid is proposed to be registered for the following uses that could result in residential exposures: Residential lawns and golf courses. EPA assessed residential exposure using the following assumptions: Because labels will include language stating that these products are to be applied by professional applicators only, residential handler exposures are not expected.

There is the potential for short-term post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with pethoxamid. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios: Incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) following a broadcast turf application. Neither an adult nor child dermal assessment was conducted because a dermal endpoint was not

selected. While not the only life stage potentially exposed for these post-application scenarios, the life stage that is included in the quantitative assessment (child 1 to less than 2 years old) is health protective for the exposures and risk estimates for any other potentially exposed life stage.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pethoxamid and any other substances, and pethoxamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pethoxamid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Pethoxamid did not cause reproductive toxicity in rats. Developmental/offspring toxicity in rats was limited to decreased body weight and was observed at the same doses that caused maternal/parental toxicity. Developmental toxicity in rabbits was limited to decreased fetal body weights and late abortions observed at the same doses that caused maternal toxicity (late abortions, clinical signs, decreased body weight, and red substance on fur/in the cage).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pethoxamid is complete.

ii. There is evidence of potential neurotoxicity in the pethoxamid database in the acute neurotoxicity study and in the developmental toxicity study in rats. However, concern is low because: (1) The observed effects are well characterized, with clear NOAELs; (2) they occur only at the highest doses tested and are likely agonal in nature; and (3) PODs are based on the most sensitive effects and are protective of any potential neurotoxicity.

iii. There is no evidence that pethoxamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pethoxamid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pethoxamid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pethoxamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pethoxamid from food and water will utilize less than 1% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pethoxamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pethoxamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pethoxamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 720 for children 1 to less than 2 years old. Because EPA's level of concern for pethoxamid is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, pethoxamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the

chronic dietary risk assessment for evaluating intermediate-term risk for pethoxamid.

5. *Aggregate cancer risk for U.S. population.* Based on the Agency's chronic risk assessment, EPA does not expect cancer risk to result from aggregate exposure to pethoxamid.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pethoxamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; Method No. AGR/MOA/PTX–8) for the determination of pethoxamid in plant commodities. Method EAS Study Code S15–03519 is proposed as the enforcement method for determination of residues of pethoxamid in livestock commodities. The extraction and analysis procedures are based on the QuEChERS method and are very similar to those of the proposed enforcement method for crop commodities, EAS Method No. AGR/MOA/PTX–8.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for pethoxamid.

C. Response to Comments

Two comments were received in response to the April 11, 2018 NOF, and 21 comments were received in response to the October 28, 2019 NOF. One comment was in support of the petition. One raised concern about bats and wind turbines that is unrelated to pesticides and this petition. The other comments were generally opposed to the Agency approving the use of pesticides on food, many stating that ''there are NO acceptable levels of pesticide residues in foods.'' Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these pethoxamid tolerances are safe. The commenters have provided no information to indicate that pethoxamid is not safe.

D. Revisions to Petitioned-For Tolerances

The following tolerances are being set at 0.01 ppm because crop field trials indicated that residues of pethoxamid were below the limit of quantitation (<0.01 ppm) in/on all soybean, cotton and corn commodities: Corn, field forage; corn, field stover; corn, sweet, forage; corn, sweet, stover; cotton gin byproducts; soybean, forage; and soybean, hay.

V. Conclusion

Therefore, tolerances are established for residues of pethoxamid, including its metabolites and degradates, in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; corn, field, forage at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; cotton, gin byproducts at 0.01 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; soybean, forage at 0.01 ppm; soybean, hay at 0.01 ppm; and soybean, seed at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian

tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 26, 2020.

Michael Goodis,

Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.710 to subpart C to read as follows:

§ 180.710 Pethoxamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pethoxamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only pethoxamid, 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenyl-1-propen-1-yl) acetamide in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husk removed	0.01
Corn, sweet, stover	0.01
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Egg	0.01
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Soybean, forage	0.01
Soybean, hay	0.01
Soybean, seed	0.01

(b) [Reserved]

[FR Doc. 2020–16452 Filed 8–11–20; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 85, No. 156
Wednesday, August 12, 2020

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

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 200806–0207]

RIN 0648–BJ18

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Amendment 21 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan

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

ACTION: Proposed rule; request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council has submitted to NMFS Amendment 21 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan. Amendment 21 proposes revisions to the summer flounder commercial state quota allocation percentages and the fishery management plan goals and objectives. Amendment 21 is intended to increase equity in state allocations when annual coastwide commercial quotas are at or above historical averages, while recognizing the economic reliance coastal communities have on the state allocation percentages currently in place.

DATES: Comments must be received by September 11, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0107, by the following method:

Electronic submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

- Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0107,*
- Click the ''Comment Now!'' icon, complete the required fields, and
- Enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of Amendment 21, including the Environmental Impact Statement, the Regulatory Impact Review, and the Initial Regulatory Flexibility Analysis (EIS/RIR/IRFA) prepared in support of this action are available from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. The supporting documents are also accessible via the internet at: *http://www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Policy Analyst, (978) 281–9116.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission cooperatively manage summer flounder under the provisions of the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP). The joint FMP became effective in 1988, establishing measures to manage summer flounder fisheries. Summer flounder is an important commercial and recreational species. Currently, 60 percent of the total allowable landings limit (TAL) is allocated to the commercial fishery (coastwide annual commercial quota), with the remaining 40 percent allocated to the recreational fishery. Available quotas are fully utilized by both sectors in most if not all fishing years.

The coastwide annual commercial quota is allocated to each of the states in the management unit (Maine-North Carolina) on a percentage basis. The existing commercial state-by-state allocations were last modified in 1993. The original allocations, adopted in 1992 as part of Amendment 2 to the FMP (December 4, 1992; 57 FR 57358), were based on available landings data from 1980–1989. Shortly thereafter, in 1993, the State of Connecticut argued that during the early and mid-1980s, the state did not have the authority to collect landings data from offshore fishermen, nor did the NMFS provide a port agent to the state that would have collected or validated landings information. Connecticut contended that their commercial landings during the allocation base years were underreported and therefore its quota share was too small. Amendment 4 (September 24, 1993; 58 FR 49937) increased Connecticut's quota share from 0.95 percent to 2.26 percent based on additional landings information provided by the state. The state-by-state allocations have not been modified since Amendment 4.

TABLE 1—CURRENT STATE-BY-STATE ALLOCATIONS

State	Current state allocation percentage
ME	0.04756
NH	0.00046
MA	6.82046
RI	15.68298
CT	2.25708
NY	7.64699
NJ	16.72499
DE	0.01779
MD	2.03910
VA	21.31676
NC	27.44584
Total	100

The current commercial allocation is perceived by many stakeholders as outdated, given that it was last modified in 1993 and is based on 1980–1989 landings data. Some other states and parties assert that the initial allocations were based on incomplete or otherwise flawed data.

Summer flounder distribution, center of biomass, and location of fishing effort has changed over time, likely due to a combination of stock rebuilding and difficult to quantify but widely accepted climate-related changes in the Mid-Atlantic Bight and southern New

England waters. As changing environmental conditions have resulted in an apparent shift in the average distribution of summer flounder, there have been requests to incorporate this information in setting state commercial quota allocations.

On September 16, 2014 (79 FR 55432), the Council published a notice of intent (NOI) to prepare an EIS for Amendment 21 to consider, in coordination with the Commission: (1) Performing a comprehensive review of all aspects of the FMP related to summer flounder; (2) updating the FMP goals and objectives for summer flounder management; and (3) modifying management strategies and measures as necessary to achieve those goals and objectives. The Council and Commission held scoping meetings during September and October of 2014 to solicit comments from the public regarding the range of commercial and recreational summer flounder management issues that should be considered in the amendment.

On March 29, 2018 (83 FR 13478), the Council published a supplemental NOI announcing that the scope of the amendment would be narrowed to include only commercial summer flounder management considerations. Due to ongoing revisions to the recreational data by the Marine Recreational Information Program, the Council and Commission chose to delay development of an amendment addressing recreational issues. This included quota allocation between the commercial and recreational sectors, as well as recreational management measures and strategies. The supplemental NOI identified that the commercial fishery-focused amendment would specifically consider revisions to the current qualification criteria for Federal moratorium permit holders, the current allocation of commercial quota, and the current list of frameworkable items in the FMP, and would consider revising the FMP goals and objectives for summer flounder.

On August 17, 2018 (83 FR 41072), the Environmental Protection Agency announced the public comment period for the Amendment 21 draft environmental impact statement (DEIS). The public comment period extended until October 12, 2018. During that time, the Council and Commission held public hearings on the DEIS in Old Lyme, Connecticut; Washington, North Carolina; Dover, Delaware; Newport News, Virginia; Buzzards Bay, Massachusetts; Narragansett, Rhode Island; Toms River, New Jersey; Berlin, Maryland; Stony Brook, New York; and via webinar.

In March 2019, the Council and the Commission's Summer Flounder, Scup, and Black Sea Bass Board approved Amendment 21 to the FMP to change the commercial quota allocation for summer flounder, as well as revise the FMP objectives for summer flounder. The Council and Commission also considered, but did not approve, changes to Federal permit qualifying criteria, and adding landings flexibility as a frameworkable subject in the FMP.

A Notice of Availability (NOA) for Amendment 21 was published in the **Federal Register** on July 29, 2020 (85 FR 16446). The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) allows us to approve, partially approve, or disapprove measures recommended by the Council in an amendment based on whether the measures are consistent with the fishery management plan, plan amendment, the Magnuson-Stevens Act and its National Standards, and other applicable law. As such, we are seeking comments in response to the NOA on whether measures in Amendment 21 are consistent with the Summer Flounder, Scup and Black Sea Bass FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law. The comment period on the NOA ends on September 28, 2020. Comments submitted on the NOA and/or this proposed rule by that date, will be considered in our decision to approve, partially approve, or disapprove Amendment 21. We will consider comments received before the end of the comment period for this proposed rule (See **DATES**) in our decision to implement measures proposed by the Council.

Proposed State-by-State Allocation Changes

Amendment 21 would change the state-by-state commercial quota allocations when the coastwide quota exceeds 9.55 million lb (4,332 mt). When the coastwide quota is 9.55 million lb (4,332 mt) or less, the quota would be distributed according to the current allocations. In years when the coastwide quota exceeds 9.55 million lb (4,332 mt), any additional quota, beyond this threshold, would be distributed in equal shares to all states except Maine, Delaware, and New Hampshire, which would split 1 percent of the additional quota. The Council and Board stated that this allocation alternative was selected over other alternatives to balance preservation of historical state access and infrastructure at recent quota levels, with an intent of providing equitability among states when the stock and quota are at high levels.

TABLE 2—PROPOSED STATE-BY-STATE ALLOCATIONS

State	Allocation of baseline quota ≤9.55 mil lb (4,332 metric tons) (percent)	Allocation of *additional* quota beyond 9.55 mil lb (4,332 metric tons) (percent)
ME	0.04756	0.333
NH	0.00046	0.333
MA	6.82046	12.375
RI	15.68298	12.375
CT	2.25708	12.375
NY	7.64699	12.375
NJ	16.72499	12.375
DE	0.01779	0.333
MD	2.03910	12.375
VA	21.31676	12.375
NC	27.44584	12.375
Total	100	100

TABLE 3—STATUS QUO STATE-BY-STATE ALLOCATIONS (IN PERCENTAGES) AND RESULTING QUOTA (IN LB) COMPARED TO THE PROPOSED REVISED ALLOCATION (IN PERCENTAGES) AND RESULTING QUOTA (IN LB) AT THE CURRENT, 2020 QUOTA LEVEL (11.53 MILLION LB)

State	Status quo state allocation percentages	Status quo distribution of 11.53 million lb quota	Revised allocation percentages (11.53 million lb quota)	Revised allocation distribution of 11.53 million lb quota	Percent change
ME	0.04756	5,484	0.09663	11,142	103.17
NH	0.00046	53	0.05762	6,644	12435.85
MA	6.82046	786,399	7.77432	896,379	13.99
RI	15.68298	1,808,248	15.11491	1,742,750	−3.62
CT	2.25708	260,241	3.99459	460,576	76.98
NY	7.64699	881,698	8.45891	975,313	10.62
NJ	16.72499	1,928,391	15.97798	1,842,262	−4.47
DE	0.01779	2,051	0.07198	8,299	304.63
MD	2.03910	235,108	3.81404	439,759	87.05
VA	21.31676	2,457,822	19.78123	2,280,776	−7.20
NC	27.44584	3,164,505	24.85779	2,866,103	−9.43
Total	100	11,530,000	100	11,530,000	0.00

TABLE 4—STATUS QUO STATE-BY-STATE ALLOCATIONS (IN PERCENTAGES) AND RESULTING QUOTA (IN MT) COMPARED TO THE PROPOSED REVISED ALLOCATION (IN PERCENTAGES) AND RESULTING QUOTA (IN MT) AT THE CURRENT, 2020 QUOTA LEVEL (5,230 MT)

State	Status quo state allocation percentages	Status quo distribution of 5,230 mt quota	Revised allocation percentages (5,230 mt quota)	Revised allocation distribution of 5,230 mt quota	Percent change
ME	0.04756	2.49	0.09663	5.05	103.17
NH	0.00046	0.02	0.05762	3.01	12435.85
MA	6.82046	356.70	7.77432	406.59	13.99
RI	15.68298	820.21	15.11491	790.50	−3.62
CT	2.25708	118.04	3.99459	208.91	76.98
NY	7.64699	399.93	8.45891	442.39	10.62
NJ	16.72499	874.70	15.97798	835.64	−4.47
DE	0.01779	0.93	0.07198	3.76	304.63
MD	2.03910	106.64	3.81404	199.47	87.05
VA	21.31676	1,114.85	19.78123	1,034.54	−7.20
NC	27.44584	1,435.39	24.85779	1,300.04	−9.43
Total	100	5,229.92	100	5,229.92	0.00

Revised Summer Flounder FMP Goals and Objectives

The original FMP objectives were adopted via Amendment 2 to the Summer Flounder FMP in 1993 and have remained unchanged since that time. Amendment 21 revises the FMP goals and objectives. While the current FMP contains only management objectives, the proposed revisions contain three overarching goals linked to more specific objectives. The proposed goals include: (1) Ensuring sustainability, of both the summer flounder stock and fishery; (2) increasing the effectiveness of management measures, through partnerships, enforcement, and data collection; and, (3) optimization of the social and economic benefits from the summer flounder stock. Additional information on these changes can be found in the EIS.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

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

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities, and also determines ways to minimize these impacts. The IRFA incorporates sections of the preamble to this rule and analyses contained in Amendment 21 and its accompanying EIS/RIR/IRFA. A copy of the complete analysis is available from the Council (see **ADDRESSES**). A summary of the IRFA follows.

Description of the Reasons Why Action by the Agency Is Being Considered and Statement of the Objectives of, and Legal Basis for, This Proposed Rule

This action proposes management measures for the commercial summer flounder fishery. This action is taken under the authority of the MSA and regulations at 50 CFR part 648. A complete description of the reasons why this action is being considered, and the objectives of and legal basis for this action, are contained in the preamble to

this proposed rule and are not repeated here.

Description and Estimate of the Number of Small Entities to Which This Proposed Rule Would Apply

The entities (*i.e.,* the small and large businesses) that may be affected by this action include fishing operations with summer flounder moratorium (commercial) permits. The recreational fishery is not impacted by this action, and therefore entities with recreational party/charter permits are not considered here; nor are private recreational anglers which are not considered ''entities'' under the RFA. For RFA purposes only, NMFS established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (50 CFR 200.2). A business primarily engaged in commercial fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million, for all its affiliated operations worldwide.

Vessel ownership data were used to identify all individuals who own commercial fishing vessels. Vessels were then grouped according to common owners. The resulting groupings were then treated as entities, or affiliates, for purposes of identifying small and large businesses which may be affected by this action. Based on this grouping, a total of 607 affiliates reported revenues from commercial summer flounder landings during the 2016–2018 period, with 601 of those business affiliates categorized as small business and 6 categorized as large business.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

There are no proposed reporting, recordkeeping, or other compliance requirements.

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

The proposed action does not duplicate, overlap, or conflict with other Federal rules.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

The proposed action (*i.e.,* the suite of preferred alternatives) includes implementation of revised commercial quota allocation system for the summer flounder fishery. Specifically, this action would create state allocations that vary with overall stock abundance and resulting commercial quotas. For all years when the annual commercial quota is at or below 9.55 million lb (4,332 mt), the state allocations would remain status quo. In years when the annual coastwide quota exceeded this trigger, the first 9.55 million lb (4,332 mt) would be distributed according to status quo allocations, and the additional quota beyond 9.55 million lb (4,332 mt) would be distributed by equal shares (with the exception of Maine, New Hampshire, and Delaware, which would split 1 percent of the additional quota).

Additional non-preferred alternatives were also considered. For the purposes of the RFA, only the preferred alternatives and those non-preferred alternatives which would minimize negative impacts to small businesses are required to be considered. Economic impacts would vary by state and community under all alternatives, but alternatives 2A (status quo) and alternatives 2C (the preferred alternative) are likely to have fewer negative impacts overall compared to other alternatives. Therefore, the preferred alternative (2C) is compared to the status quo (alternative 2A) in the quantitative analysis. Although not required, we also provide a brief summary of the relative impacts of the two additional non-preferred options (2B and 2D).

The analysis was conducted assuming full utilization of the 2020 commercial quota of 11.53 million lb (5,230 mt). Results indicate that the proposed action of a quota reallocation threshold of 9.55 million lb (4,332 mt) increases fleetwide revenue by $0.4 million relative to No Action and ex-vessel price by $0.04 per pound relative to No Action. The proposed action is estimated to yield a decrease in fishery-wide revenue of $0.15 million as compared to the quota reallocation threshold of 8.4 million lb (3,810 mt) (Alternative 2C–1). This slight decrease in revenue under the proposed action, relative to the highest revenue-generating alternative, is not expected to disproportionately impact small entities.

Additional alternatives, 2B and 2D, were considered but not recommended by the Council. Alternatives 2B and 2D had more negative impacts on small businesses than the selected alternative. Alternative 2B considered revisions to the quota allocation based on recent summer flounder biomass distribution, alternative 2D, the ''scup model'', considered a significant change in summer flounder management by creating a winter season that was open to any vessel with a summer flounder permit.

Compared to the other allocation alternatives, the impacts of alternative 2D are the most difficult to determine, as this alternative is associated with the highest uncertainty regarding impacts on vessel participation, fishing effort, landings patterns, and market responses. Relative to alternative 2A, alternative 2D is expected to have a higher magnitude of positive or negative impacts to states and businesses, due to the substantial change in the management system that will benefit some and negatively impact others. Shoreside communities would also be impacted by alternative 2D. Many states have invested heavily in shoreside infrastructure to support their fleets. Under alternative 2D, the distribution of landings in the winter would be driven more by vessel preference and market factors, which would positively impact some shoreside businesses and negatively impact others.

Alternative 2B would shift quota allocation from the Southern region of the management unit (North Carolina through New Jersey) to the Northern region (New York through Maine). Compared to alternative 2C, alternative 2B is more likely to have a higher magnitude of positive or negative impacts (depending on the state), as allocation changes would be permanently revised from status quo, while under 2C there is the potential for status quo allocation. Additionally, option 2C has a higher likelihood of costs and benefits being shared more equally over time as the quota fluctuates above and below the trigger point.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: August 6, 2020.

Donna S. Wieting,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.102, paragraph (c)(1) is revised to read as follows:

§ 648.102 Summer flounder specifications.

* * * * *

(c) * * *

(1) *Distribution of annual commercial quota.* (i) For years when the annual commercial quota is at or below 9,550,000 lb (4,332 mt), the quota will be distributed to the states, based upon the following percentages (state followed by percent share in parenthesis): Maine (0.04756); New Hampshire (0.00046); Massachusetts (6.82046); Rhode Island (15.68298); Connecticut (2.25708); New York (7.64699); New Jersey (16.72499); Delaware (0.01779); Maryland (2.03910); Virginia (21.31676); and North Carolina (27.44584).

(ii) For years when the annual commercial quota is greater than 9,550,000 lb (4,332 mt), the quota up to 9.55 million lb (4,332 mt) will be distributed as outlined in paragraph (c)(1)(i) of this section and the additional quota above 9.55 million lb will be distributed based upon the following percentages (state followed by percent share in parenthesis): Maine (0.333); New Hampshire (0.333); Massachusetts (12.375); Rhode Island (12.375); Connecticut (12.375); New York (12.375); New Jersey (12.375); Delaware (0.333); Maryland (12.375); Virginia (12.375); and North Carolina (12.375).

* * * * *

[FR Doc. 2020–17609 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 85, No. 156

Wednesday, August 12, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois Advisory Committee, Amendment

AGENCY: Commission on Civil Rights.

ACTION: Notice; amendment to meeting date.

SUMMARY: The Commission on Civil Rights is holding a meeting of the Illinois Advisory Committee on Wednesday, August 12, 2020 at 1:00 p.m. CDT. This notice serves as an amendment to the initially supplied date of Tuesday, August 4, 2020 at 1:00 p.m. CDT.

FOR FURTHER INFORMATION CONTACT: Carolyn Allen, (312) 353–8311, *callen@usccr.gov.*

Amendment: Date of Tuesday, August 4, 2020 at 1:00 p.m. to be replaced with new meeting date of Wednesday, August 12, 2020 at 1:00 p.m. CDT.

Dated: August 6, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–17588 Filed 8–11–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–857, A–580–870, A–489–816, A–823–815, A–552–817, C–533–858, C–489–817]

Oil Country Tubular Goods From India, the Republic of Korea, the Republic of Turkey, Ukraine, and the Socialist Republic of Vietnam: Continuation of Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that the revocation of the antidumping duty (AD) orders on certain oil country tubular goods (OCTG) from India, the Republic of Korea (Korea), the Republic of Turkey (Turkey), Ukraine, and the Socialist Republic of Vietnam (Vietnam) and countervailing duty (CVD) orders on OCTG from India and Turkey would likely lead to the continuation or recurrence of dumping or countervailable subsidies, and of material injury to an industry in the United States. Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Chelsey Simonovich, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1979.

SUPPLEMENTARY INFORMATION:

Background

In 2014, Commerce published the AD orders on OCTG from India, Korea, Turkey, and Vietnam and the CVD orders on OCTG from India and Turkey; in 2019, Commerce published the AD order on OCTG from Ukraine.[1] On February 5, 2019, the ITC instituted,[2] and on June 4, 2019 Commerce initiated,[3] the five-year (sunset) reviews of the AD and CVD orders on OCTG from India, Korea, Turkey, Ukraine, and Vietnam, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* would be likely to lead to the continuation or recurrence of dumping or the continuation or recurrence of countervailable subsidies, and, therefore, notified the ITC of the magnitude of the margins of dumping and the net subsidy rates likely to prevail should the *Orders* be revoked.[4] On August 3, 2020, the ITC published its determinations, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

For purposes of these *Orders* and a complete description of the products covered by each order, please see the *Final Results* and accompanying Issues and Decision Memoranda.[6]

[1] *See Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691 (September 10, 2014); *see also Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Notice of Correction to the Antidumping Duty Orders with Respect to Turkey and the Socialist Republic of Vietnam,* 79 FR 59740 (October 3, 2014); *Certain Oil Country Tubular Goods from India and the Republic of Turkey: Countervailing Duty Orders and Amended Final Countervailing Duty Determination for India,* 79 FR 53688 (September 10, 2014); and *Termination of the Suspension Agreement on Certain Oil Country Tubular Goods from Ukraine, Rescission of Administrative Review, and Issuance of Antidumping Duty Order,* 84 FR 33918 (July 16, 2019) (collectively, *Orders*).

[2] *See Oil Country Tubular Goods from India, Korea, Turkey, Ukraine, and Vietnam; Institution of Five-Year Reviews,* 84 FR 25570 (June 3, 2019).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 84 FR 1705 (February 5, 2019).

[4] *See Oil Country Tubular Goods from India: Final Results of the Expedited Sunset Review of the Countervailing Duty Order,* 84 FR 50001 (September 24, 2019), and accompanying Issues and Decision Memorandum (IDM); *see also Oil Country Tubular Goods from the Republic of Turkey: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 84 FR 55139 (October 15, 2019), and accompanying IDM; *Certain Oil Country Tubular Goods from India, the Republic of Korea, Turkey, and the Socialist Republic of Vietnam: Final Results of Expedited First Sunset Reviews of the Antidumping Duty Orders,* 85 FR 12774 (March 4, 2020), and accompanying IDM; and *Oil Country Tubular Goods from Ukraine: Final Results of the First Five-Year Sunset Review of the Antidumping Duty Order,* 85 FR 27206 (May 7, 2020), and accompanying IDM.

[5] *See Oil Country Tubular Goods from India, Korea, Turkey, Ukraine, and Vietnam (Inv. Nos. 701–TA–499–500 and 731–TA–1215–1216 and 1221–1223 (Review)),* 85 FR 46729 (August 3, 2020); *see also Oil Country Tubular Goods from India, Korea, Turkey, Ukraine, and Vietnam (Inv. Nos. 701–TA–499–500 and 731–TA–1215–1216 and 1221–1223 (Review)),* USITC Pub. 5090 (July 2020).

[6] *See Oil Country Tubular Goods from India: Final Results of the Expedited Sunset Review of the Countervailing Duty Order,* 84 FR 50001 (September 24, 2019), and accompanying IDM; *see also Oil Country Tubular Goods from the Republic of Turkey: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 84 FR 55139 (October 15, 2019), and accompanying IDM; *Certain Oil Country Tubular Goods from India, the Republic of Korea, Turkey, and the Socialist Republic of Vietnam: Final Results of Expedited First Sunset Reviews of the Antidumping Duty Orders,* 85 FR 12774 (March 4, 2020), and accompanying IDM; and *Oil Country Tubular Goods from Ukraine: Final Results of the First Five-Year*

Continued

Continuation of the *Orders*

As a result of the determinations by Commerce and the ITC that revocation the *Orders* would likely lead to the continuation or recurrence of dumping or countervailable subsidies and the continuation or recurrence of material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply is a violation of the APO which may be subject to sanctions.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: August 6, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–17632 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–DS–P

Sunset Review of the Antidumping Duty Order, 85 FR 27206 (May 7, 2020), and accompanying IDM.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–829]

Passenger Vehicle and Light Truck Tires From the Socialist Republic of Vietnam: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Romani or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0198 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 22, 2020, the Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of passenger vehicle and light truck tires from the Socialist Republic of Vietnam.[1] Currently, the preliminary determination is due no later than August 26, 2020.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.[2]

On July 24 and August 4, 2020, the petitioner[3] submitted timely requests that Commerce postpone the preliminary CVD determination.[4] According to the petitioner, additional time is necessary ''to permit Commerce to review respondents' initial full questionnaire responses, any comments thereon and rebuttal factual information filed in response, and any supplemental questionnaire responses before determining preliminary subsidy rates.''[5] The petitioner further elaborates that an extension of the deadline for the preliminary results is warranted ''{g}iven the number of programs under investigation, including Commerce's first investigation of a currency undervaluation subsidy under its new rules.''[6] Consistent with 19 CFR 351.205(e), the petitioner stated the reasons for its request, and Commerce finds no compelling reason to deny that request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, until October 30, 2020. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: August 4, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–17631 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Passenger Vehicle and Light Truck Tires from the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigation,* 85 FR 38850 (June 29, 2020).

[2] *See* 19 CFR 351.205(e).

[3] The petitioner is the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC.

[4] *See* Petitioner's Letter, ''Passenger Vehicle and Light Truck Tires from Vietnam: Request to Extend Deadline for Preliminary Determination,'' dated July 24, 2020 (First Request); and Petitioner's Letter, ''Passenger Vehicle and Light Truck Tires from Vietnam: Second Request to Extend Deadline for Preliminary Determination,'' dated August 4, 2020 (Second Request).

[5] *See* First Request at 1; and Second Request at 1.

[6] *See* First Request at 2; and Second Request at 2.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–853]

Wood Mouldings and Millwork Products From Brazil: Preliminary Negative Determination of Sales at Less Than Fair Value and Postponement of Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that wood mouldings and millwork products (millwork products) from Brazil are not being, or are not likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2019 through December 31, 2019. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 12, 2020.

FOR FURTHER INFORMATION CONTACT: George Ayache or Suzanne Lam, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2623 or (202) 482–0783, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 5, 2020.[1] On May 26, 2020, Commerce postponed the preliminary determination of this investigation and the revised deadline is now August 5, 2020.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are millwork products from Brazil. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice,* as well as additional language proposed by Commerce. For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Determination

For this preliminary determination, Commerce calculated a zero estimated weighted-average dumping margin for the individually examined producer and/or exporter of the subject merchandise. Consistent with section 733(b)(3) of the Act, Commerce disregards *de minimis* rates and preliminarily determines that the individually examined respondent with a *de minimis* rate has not made sales of subject merchandise at LTFV during the POI.

Exporter/producer	Estimated weighted-average dumping margin (percent)
Araupel S.A./Braslumber Industria de Molduras Ltda./BrasPine Madeiras Ltda.[7]	0.00

Consistent with section 733(d) of the Act, Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters, because it has not made an affirmative preliminary determination of sales at LTFV.

Suspension of Liquidation

Because Commerce has made a negative preliminary determination of sales at LTFV with regard to subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation or to require a cash deposit of estimated antidumping duties for any such entries.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit case and rebuttal briefs on the preliminary scope determination. The deadline to submit

[1] *See Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 6502 (February 5, 2020) (*Initiation Notice*).

[2] *See Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 85 FR 31459 (May 26, 2020).

[3] *See* Memorandum, ''Wood Mouldings and Millwork Products from Brazil: Decision Memorandum for the Preliminary Negative Determination in the Less-Than-Fair-Value Investigation,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this preliminary determination (Preliminary Scope Decision Memorandum).

[7] Commerce preliminarily determines that Araupel S.A., Braslumber Industria de Molduras Ltda., and Braspine Madeiras Ltda. are a single entity. *See* Preliminary Decision Memorandum; *see also* Memorandum, ''Less-Than-Fair-Value Investigation of Wood Mouldings and Millwork Products from Brazil: Preliminary Affiliation and Collapsing Determination for Araupel S.A., Braslumber Industria de Molduras Ltda., and Braspine Madeiras Ltda.,'' dated August 5, 2020.

these comments will be no later than 30 days after the publication of this preliminary determination. Scope rebuttal briefs (which are limited to issues raised in the scope briefs) may be submitted no later than seven days after the deadline for the scope briefs. For all scope briefs and rebuttals thereto, parties must file identical documents simultaneously on the records of all the ongoing AD and CVD millwork products investigations. No new factual information or business proprietary information may be included in either scope briefs or rebuttal scope briefs.

Case briefs or other written comments regarding non-scope matters may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[8] Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date.

Postponement of Final Determination

Section 735(a)(2)(B) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. On July 9, 2020, the petitioner requested that Commerce postpone the final determination.[10] In accordance with section 735(a)(2)(B) of the Act, because the preliminary determination is negative, and the petitioner has requested the postponement of the final determination, Commerce is postponing the final determination. Accordingly, Commerce will make its final determination by no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine 75 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: August 5, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation consists of wood mouldings and millwork products that are made of wood (regardless of wood species), bamboo, laminated veneer lumber (LVL), or of wood and composite materials (where the composite materials make up less than 50 percent of the total merchandise), and which are continuously shaped wood or finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The merchandise subject to this investigation can be continuously shaped along any of its edges, ends, or faces.

The percentage of composite materials contained in a wood moulding or millwork product is measured by length, except when the composite material is a coating or cladding. Wood mouldings and millwork products that are coated or clad, even along their entire length, with a composite material, but that are otherwise comprised of wood, LVL, or wood and composite materials (where the non-coating composite materials make up 50 percent or less of the total merchandise) are covered by the scope.

The merchandise subject to this investigation consists of wood, LVL, bamboo, or a combination of wood and composite materials that is continuously shaped throughout its length (with the exception of any endwork/dados), profiled wood having a repetitive design in relief, similar milled wood architectural accessories, such as rosettes and plinth blocks, and finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The scope includes continuously shaped wood in the forms of dowels, building components such as interior paneling and jamb parts, and door components such as rails, stiles, interior and exterior door frames or jambs (including split, flat, stop applied, single- or double-rabbeted), frame or jamb kits, and packaged door frame trim or casing sets, whether or not the door components are imported as part of a door kit or set.

The covered products may be solid wood, laminated, finger-jointed, edge-glued, face-glued, or otherwise joined in the production or remanufacturing process and are covered by the scope whether imported raw, coated (*e.g.,* gesso, polymer, or plastic), primed, painted, stained, wrapped (paper or vinyl overlay), any combination of the aforementioned surface coatings, treated, or which incorporate rot-resistant elements (whether wood or composite). The covered products are covered by the scope whether or not any surface coating(s) or covers obscures the grain, textures, or markings of the wood, whether or not they are ready for use or require final machining (*e.g.,* endwork/dado, hinge/strike machining, weatherstrip or application thereof, mitre) or packaging.

All wood mouldings and millwork products are included within the scope even if they are trimmed; cut-to-size; notched; punched; drilled; or have undergone other forms of minor processing.

Subject merchandise also includes wood mouldings and millwork products that have been further processed in a third country, including but not limited to trimming, cutting, notching, punching, drilling, coating, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation are countertop/butcherblocks, exterior fencing, exterior decking and exterior siding products (including solid wood siding, non-wood siding (*e.g.,* composite or cement), and shingles) that are not LVL or finger jointed; finished and unfinished doors; flooring; parts of stair steps (including newel posts, balusters, easing, gooseneck, risers, treads, rail fittings and stair stringers); picture frame components three feet and under in individual lengths; and lumber whether solid, finger-jointed, or edge-glued. To be excluded from the scope, finger-jointed or edge-glued lumber must have a nominal thickness greater than 1.5 inches and a certification stamp from an American Lumber Standard Committee-certified grading bureau. The exclusion for lumber whether solid, finger-jointed, or edge-glued

[8] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[10] *See* Petitioner's Letter, ''Wood Mouldings and Millwork Products from Brazil: Petitioner's Request for Postponement of the Final Determination,'' dated July 9, 2020.

does not apply to screen/''surfaced on 4 sides'' (S4S) and/or ''surface 1 side, 2 edges'' (SlS2E) stock (also called boards) that are finger-jointed, edge-glued mouldings, or millwork blanks (whether or not resawn).

Imports of wood mouldings and millwork products are primarily entered under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 4409.10.4010, 4409.10.4090, 4409.10.4500, 4409.10.5000, 4409.22.4000, 4409.22.5000, 4409.29.4100, and 4409.29.5100. Imports of wood mouldings and millwork products may also enter under HTSUS numbers: 4409.10.6000, 4409.10.6500, 4409.22.6000, 4409.22.6500, 4409.29.6100, 4409.29.6600, 4418.20.4000, 4418.20.8030, 4418.20.8060, 4418.99.9095 and 4421.99.9780. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Affiliation/Single Entity
V. Discussion of the Methodology
VI. Currency Conversion
VII. Conclusion

[FR Doc. 2020–17638 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–117]

Wood Mouldings and Millwork Products From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that wood mouldings and millwork products (millwork products) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2019 through December 31, 2019. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Bowen or Brian Smith, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0768 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 5, 2020.[1] On May 26, 2020, Commerce postponed the preliminary determination of this investigation and the revised deadline is now August 5, 2020.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are millwork products from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice,* as well as additional language proposed by Commerce. For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act and constructed export prices in accordance with section 772(b) of the Act. Because China is a non-market economy, within the meaning of section 771(18) of the Act, Commerce has calculated normal value in accordance with section 773(c) of the Act. Furthermore, pursuant to section 776(a) and (b) of the Act, Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for the China-wide Entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[7] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[8]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

[1] *See Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 6502 (February 5, 2020) (*Initiation Notice*).

[2] *See Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 85 FR 31459 (May 26, 2020).

[3] *See* Memorandum, ''Wood Mouldings and Millwork Products from the People's Republic of China: Decision Memorandum for Preliminary Affirmative Determination of Sales at Less-Than-Fair-Value,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice*.

[6] *See* Memorandum, ''Wood Mouldings and Millwork Products from Brazil and the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this preliminary determination (Preliminary Scope Decision Memorandum).

[7] *See Initiation Notice* at 85 FR 6507.

[8] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[9] Commerce preliminarily determines that Yinfeng/Mangrove are a single entity. *See* Preliminary Decision Memorandum.

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Bel Trade Wood Industrial Co., Ltd. Youxi Fujian	Bel Trade Wood Industrial Co., Ltd. Youxi Fujian	146.91	136.18
Fujian Yinfeng Imp & Exp Trading Co., Ltd./Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.[9]	Fujian Yinfeng Imp & Exp Trading Co., Ltd./Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.	40.30	29.57
Anji Golden Elephant Bamboo Wooden Industry Co., Ltd.	Anji Golden Elephant Bamboo Wooden Industry Co., Ltd.	79.40	68.67
Anji Huaxin Bamboo & Wood Products Co., Ltd	Anji Huaxin Bamboo & Wood Products Co., Ltd	79.40	68.67
Cao County Hengda Wood Products Co., Ltd	Cao County Hengda Wood Products Co., Ltd	79.40	68.67
Evermark (Yantai) Co., Ltd	Evermark (Yantai) Co., Ltd	79.40	68.67
Fujian Hongjia Craft Products Co., Ltd	Fujian Hongjia Craft Products Co., Ltd	79.40	68.67
Fujian Jinquan Trade Co., Ltd	Fujian Province Youxi County Baiyuan Wood Machining Co., Ltd.	79.40	68.67
Fujian Nanping Yuanqiao Wood Industry Co., Ltd	Fujian Nanping Yuanqiao Wood Industry Co., Ltd	79.40	68.67
Fujian Province Youxi County Chang Sheng Wood Machining Co., Ltd.	Fujian Province Youxi County Chang Sheng Wood Machining Co., Ltd.	79.40	68.67
Fujian Sanming City Donglai Wood Co., Ltd	Fujian Sanming City Donglai Wood Co., Ltd	79.40	68.67
Fujian Shunchang Shengsheng Wood Industry Limited Company.	Fujian Shunchang Shengsheng Wood Industry Limited Company.	79.40	68.67
Fujian Wangbin Decorative Material Co., Ltd	Fujian Wangbin Decorative Material Co., Ltd	79.40	68.67
Fujian Youxi Best Arts & Crafts Co., Ltd	Fujian Ruisen International Industrial Co., Ltd	79.40	68.67
Fujian Zhangping Kimura Forestry Products Co., Ltd	Fujian Zhangping Kimura Forestry Products Co., Ltd	79.40	68.67
Heze Huasheng Wooden Co., Ltd	Heze Huasheng Wooden Co., Ltd	79.40	68.67
Huaan Longda Wood Industry Co., Ltd	Huaan Longda Wood Industry Co., Ltd	79.40	68.67
Jiangsu Chen Sheng Forestry Development Co., Ltd	Jiangsu Chen Sheng Forestry Development Co., Ltd	79.40	68.67
Jiangsu Wenfeng Wood Co., Ltd	Jiangsu Wenfeng Wood Co., Ltd	79.40	68.67
Lianyungang Tianke New Energy Technology Co., Ltd	Lianyungang Tianke New Energy Technology Co., Ltd	79.40	68.67
Longquan Jiefeng Trade Co., Ltd	Zhejiang Senya Board Industry Co., Ltd	79.40	68.67
Nanping Huatai Wood & Bamboo Co., Ltd	Nanping Huatai Wood & Bamboo Co., Ltd	79.40	68.67
Nanping Qiangmei Import & Export Co., Ltd	Pucheng County Qiangmei Wood Company, Ltd	79.40	68.67
Oppein Home Group Inc	Oppein Home Group Inc	79.40	68.67
Putian Yihong Wood Industry Co., Ltd	Putian Yihong Wood Industry Co., Ltd	79.40	68.67
Qimen Jianxing Bamboo and Wood Goods Co., Ltd	Qimen Jianxing Bamboo and Wood Goods Co., Ltd	79.40	68.67
Qingdao Sanhe Dacheng International Trade Co., Ltd	Yongan Tenlong Bamboo & Wood Products Co., Ltd	79.40	68.67
Rizhao Duli Trade Co., Ltd	Rizhao Jiayue Industry & Trading Co., Ltd	79.40	68.67
Rizhao Guantong Woodworking Co., Ltd	Shouguang Luli Wood Industry Co., Ltd./Rizhao Forest International Trading Co., Ltd./Xiamen Oubai Industry & Trade. Co., Ltd.	79.40	68.67
Sanming Lingtong Trading Co., Ltd	Sanming Shitong Wood Industry Co., Ltd	79.40	68.67
Shandong Miting Household Co., Ltd	Shandong Jicheng Decorative Material Co., Ltd	79.40	68.67
Shaxian Hengtong Wood Industry Co., Ltd	Shaxian Hengtong Wood Industry Co., Ltd	79.40	68.67
Shaxian Shiyiwood, Ltd	Shaxian Shiyiwood, Ltd	79.40	68.67
Shuyang Kevin International Co., Ltd	Shuyang Zhongding Decoration Materials Co., Ltd	79.40	68.67
Suqian Sulu Import & Export Trading Co., Ltd	Suqian Sulu Import & Export Trading Co., Ltd	79.40	68.67
The Ancientree Cabinet Co., Ltd	The Ancientree Cabinet Co., Ltd	79.40	68.67
Xiamen Jinxi Building Material Co., Ltd	Zhangzhou City Jinxi Building Material Co., Ltd	79.40	68.67
Xuzhou Goodwill Resource Co., Ltd	Pucheng County Qiangmei Wood Company, Ltd./Lianyungang Tianke New Energy Technology Co., Ltd./Fujian Sanming City Donglai Wood Co., Ltd./Zhangzhou Fukangyuan Industry and Trade Co., Ltd.	79.40	68.67
Xuzhou Hexi Wood Co., Ltd	Xuzhou Hexi Wood Co., Ltd	79.40	68.67
Zhangping San Chuan Industrial & Trade Co., Ltd	Zhangping San Chuan Industrial & Trade Co., Ltd	79.40	68.67
Zhangzhou Green Wood Industry and Trade Co., Ltd	Zhangzhou Green Wood Industry and Trade Co., Ltd	79.40	68.67
Zhangzhou Wangjiamei Industry and Trade Co., Ltd	Zhangzhou Wangjiamei Industry and Trade Co., Ltd	79.40	68.67
Zhangzhou Yihong Industrial Co., Ltd	Zhangzhou Yihong Industrial Co., Ltd	79.40	68.67
China-Wide Entity		359.16	348.43

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise, as described in the scope of the investigation section, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above, as follows: (1) For the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of subject merchandise that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all

third-county exporters of subject merchandise not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the Preliminary Determination Section's chart of estimated weighted-average dumping margins above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit case and rebuttal briefs on the preliminary scope determination. The deadline to submit these comments will be no later than 30 days after the publication of this preliminary determination. Scope rebuttal briefs (which are limited to issues raised in the scope briefs) may be submitted no later than seven days after the deadline for the scope briefs. For all scope briefs and rebuttals thereto, parties must file identical documents simultaneously on the records of all the ongoing AD and CVD millwork products investigations. No new factual information or business proprietary information may be included in either scope briefs or rebuttal scope briefs.

Case briefs or other written comments regarding non-scope matters may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[10] Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On July 2, 2020, pursuant to 19 CFR 351.210(e), the mandatory respondents, Bel Trade Wood Industrial Co., Ltd. Youxi Fujian (Bel Trade) and Fujian Yinfeng Imp & Exp Trading Co., Ltd. (Yinfeng), requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[12] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[12] *See* Bel Trade's and Yinfeng's Letter, ''Wood Mouldings and Millwork Products from the People's Republic of China: Respondents' Request to Postpone Final Determination and Extend Deadline for Malaysian Surrogate Financial Statements,'' dated July 2, 2020.

Dated: August 5, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation consists of wood mouldings and millwork products that are made of wood (regardless of wood species), bamboo, laminated veneer lumber (LVL), or of wood and composite materials (where the composite materials make up less than 50 percent of the total merchandise), and which are continuously shaped wood or finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The merchandise subject to this investigation can be continuously shaped along any of its edges, ends, or faces.

The percentage of composite materials contained in a wood moulding or millwork product is measured by length, except when the composite material is a coating or cladding. Wood mouldings and millwork products that are coated or clad, even along their entire length, with a composite material, but that are otherwise comprised of wood, LVL, or wood and composite materials (where the non-coating composite materials make up 50 percent or less of the total merchandise) are covered by the scope.

The merchandise subject to this investigation consists of wood, LVL, bamboo, or a combination of wood and composite materials that is continuously shaped throughout its length (with the exception of any endwork/dados), profiled wood having a repetitive design in relief, similar milled wood architectural accessories, such as rosettes and plinth blocks, and finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The scope includes continuously shaped wood in the forms of dowels, building components such as interior paneling and jamb parts, and door components such as rails, stiles, interior and exterior door frames or jambs (including split, flat, stop applied, single- or double-rabbeted), frame or jamb kits, and packaged door frame trim or casing sets, whether or not the door components are imported as part of a door kit or set.

The covered products may be solid wood, laminated, finger-jointed, edge-glued, face-glued, or otherwise joined in the production or remanufacturing process and are covered by the scope whether imported raw, coated (*e.g.,* gesso, polymer, or plastic), primed, painted, stained, wrapped (paper or vinyl overlay), any combination of the aforementioned surface coatings, treated, or which incorporate rot-resistant elements (whether wood or composite). The covered products are covered by the scope whether or not any surface coating(s) or covers obscures the grain, textures, or markings of the wood, whether or not they are ready for use or require final machining (*e.g.,* endwork/dado, hinge/strike machining, weatherstrip or application thereof, mitre) or packaging.

All wood mouldings and millwork products are included within the scope even if they are trimmed; cut-to-size; notched; punched; drilled; or have undergone other forms of minor processing.

Subject merchandise also includes wood mouldings and millwork products that have been further processed in a third country, including but not limited to trimming, cutting, notching, punching, drilling, coating, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation are countertop/butcherblocks, exterior fencing, exterior decking and exterior siding products (including solid wood siding, non-wood siding (*e.g.,* composite or cement), and shingles) that are not LVL or finger jointed; finished and unfinished doors; flooring; parts of stair steps (including newel posts, balusters, easing, gooseneck, risers, treads, rail fittings and stair stringers); picture frame components three feet and under in individual lengths; and lumber whether solid, finger-jointed, or edge-glued. To be excluded from the scope, finger-jointed or edge-glued lumber must have a nominal thickness greater than 1.5 inches and a certification stamp from an American Lumber Standard Committee-certified grading bureau. The exclusion for lumber whether solid, finger-jointed, or edge-glued does not apply to screen/''surfaced on 4 sides'' (S4S) and/or ''surface 1 side, 2 edges'' (SlS2E) stock (also called boards) that are finger-jointed, edge-glued mouldings, or millwork blanks (whether or not resawn).

Excluded from the scope of this investigation are all products covered by the scope of the antidumping duty order on *Hardwood Plywood from the People's Republic of China. See Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 83 FR 504 (January 4, 2018).

Excluded from the scope of this investigation are all products covered by the scope of the antidumping duty order on *Multilayered Wood Flooring from the People's Republic of China. See Multilayered Wood Flooring from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 76 FR 76690 (December 8, 2011).

Excluded from the scope of this investigation are all products covered by the scope of the antidumping duty order on *Wooden Cabinets and Vanities from the People's Republic of China. See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 85 FR 22126 (April 21, 2020).

Excluded from the scope of this investigation are all products covered by the scope of the antidumping duty order on *Wooden Bedroom Furniture from the People's Republic of China. See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China,* 70 FR 329 (January 4, 2005).

Imports of wood mouldings and millwork products are primarily entered under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 4409.10.4010, 4409.10.4090, 4409.10.4500, 4409.10.5000, 4409.22.4000, 4409.22.5000, 4409.29.4100, and 4409.29.5100. Imports of wood mouldings and millwork products may also enter under HTSUS numbers: 4409.10.6000,4409.10.6500, 4409.22.6000, 4409.22.6500, 4409.29.6100, 4409.29.6600, 4418.20.4000, 4418.20.8030, 4418.20.8060, 4418.99.9095 and 4421.99.9780. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Discussion of the Methodology
V. Currency Conversion
VI. Adjustment Under Section 777(A)(f) of the Act
VII. Adjustment for Countervailable Export Subsidies
VIII. Conclusion

[FR Doc. 2020–17637 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–833]

Citric Acid and Certain Citrate Salts From Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sales of citric acid and certain citrate salts (citric acid) from Thailand were made by COFCO Biochemical (Thailand) Co., Ltd. (COFCO) and Niran (Thailand) Co., Ltd. (Niran) at less than normal value (NV) during the period of review (POR) January 8, 2018 through June 30, 2019. We also find that Sunshine Biotech International Co., Ltd. (Sunshine) did not sell citric acid at less than NV during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 12, 2020.

FOR FURTHER INFORMATION CONTACT: Joy Zhang or Jolanta Lawska, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone:

(202) 482–1168 or (202) 482–8362, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2018, Commerce published the *Citric Acid Order* in the **Federal Register**.[1] On September 9, 2019, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the *Citric Acid Order* covering COFCO, Niran, and Sunshine.[2] On March 2, 2020, Commerce extended the deadline for the preliminary results to July 30, 2020.[3] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[4] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[5] The deadline for the preliminary results of this review is now November 17, 2020. For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6]

Scope of the Order

The merchandise covered by this review includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. Export price and constructed export price were calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). A complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins exist for the POR:

Exporter/producer	Weighted-average dumping margin (percent)
COFCO Biochemical (Thailand) Co., Ltd. (COFCO)	0.76
Niran (Thailand) Co., Ltd	54.11
Sunshine Biotech International Co., Ltd	0.00 (*de minimis*)

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for listed above companies are not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[7] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.5 percent). Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by each respondent which did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate entries not reviewed at the all-others rate of 11.25 percent if there is no rate for the intermediate company(ies) involved in the transaction. We intend to issue instructions to CBP 15 days after publication of the final results of this review.[8]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of citric acid from Thailand entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the firms listed above will be equal to the dumping margins established in the final results of this review, except if the ultimate rates are *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rates will be zero; (2) for merchandise exported by

[1] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Citric Acid Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 47242 (September 9, 2019).

[3] *See* Memorandum, ''Citric Acid from Thailand: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review; 2018/2019,'' dated March 2, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Citric Acid and Certain Citrate Salts from Thailand; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] In the preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

[8] *See* 19 CFR 356.8(a).

producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 11.25 percent, the all-others rate established in the antidumping duty investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose to the parties to the proceeding the calculations performed in connection with these preliminary results to interested parties within five days of publication of this notice.[10]

Interested parties may submit case briefs to Commerce in response to these preliminary results no later than 30 days after the publication of this notice.[11] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[12] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13] Case and rebuttal briefs should be filed using ACCESS.[14] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request for a hearing must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[16] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[17]

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of these preliminary results in the **Federal Register**, unless otherwise extended.[18]

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: August 5, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2020–17639 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See Citric Acid Order.*

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(c)(1)(ii).

[12] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

[14] *See generally* 19 CFR 351.303.

[15] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[16] *See* 19 CFR 351.310(c); *see also* 19 CFR 351.303(b)(1).

[17] *See* 19 CFR 351.310(d).

[18] *See* section 751(a)(3)(A) of the Act.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

ENVIRONMENTAL PROTECTION AGENCY

Coastal Nonpoint Pollution Control Program: Intent To Find That Washington Has Satisfied All Conditions of Approval Placed on Its Coastal Nonpoint Pollution Control Program

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce, and U.S. Environmental Protection Agency.

ACTION: Notice of availability of proposed finding; extension to public comment period.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) and the U.S. Environmental Protection Agency (EPA) (the agencies) hereby extend the comment period on the agencies' proposed finding that Washington has satisfied all conditions the agencies established as part of their 1998 approval of the State's coastal nonpoint pollution control program (coastal nonpoint program) under Section 6217 of the Coastal Zone Act Reauthorization Amendments (CZARA).

DATES: The comment period for the proposed findings published June 15, 2020, at 85 FR 36186, is extended to September 14, 2020.

ADDRESSES: Comments may be submitted by:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/docket?D=NOAA-NOS-2019-0135,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Joelle Gore, Chief, Stewardship Division (N/OCM6), Office for Coastal Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910; phone (240) 533–0813; ATTN: Washington Coastal Nonpoint Program.

Instructions: All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personally identifiable information (name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the commenter will be publicly accessible. NOAA and EPA will accept anonymous comments (enter ''N/A'' in the required fields if you wish

to remain anonymous). Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The agencies will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system).

FOR FURTHER INFORMATION CONTACT: Copies of the proposed findings document may be found on *www.regulations.gov/docket?D=NOAA-NOS-2019-0135* and NOAA's Coastal Nonpoint Pollution Control Program website at *https://coast.noaa.gov/czm/pollutioncontrol/.* Additional background information on the State's program may be obtained upon request from: Allison Castellan, Stewardship Division (N/OCM6), Office for Coastal Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland 20910, phone (240) 533–0799, email: *allison.castellan@noaa.gov;* or Michelle Wilcox, U.S. EPA Region 10, Washington Operations Office, 300 Desmond Drive SE, Suite 102, Lacey, WA 98503, phone: (360) 753–9469, email: *wilcox.michelle@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 15, 2020, NOAA and EPA announced the availability of proposed findings on Washington's Coastal Nonpoint Program; see 85 FR 36186 for more complete information about the agencies' proposed finding. The original 60-day public comment period was set to end on August 14, 2020. This notice extends the comment period by 30 days to provide additional time for public comment.

Nicole R. LeBoeuf,

Deputy Assistant Administrator for Ocean Services, National Oceanic and Atmospheric Administration.

David P. Ross,

Assistant Administrator, Office of Water, Environmental Protection Agency.

[FR Doc. 2020–17627 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA370]

Western Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold meetings of its American Samoa Archipelago Fishery Ecosystem Plan (FEP) Advisory Panel (AP), Hawaii Archipelago FEP AP, Mariana Archipelago FEP-Guam AP, and Mariana Archipelago FEP-Commonwealth of the Northern Mariana Islands (CNMI) AP to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The American Samoa Archipelago FEP AP will meet on Wednesday, August 26, 2020, from 5 p.m. to 7 p.m.; the Hawaii Archipelago FEP AP will meet on Thursday, August 27, 2020, from 9 a.m. to 11 a.m.; the Mariana Archipelago FEP-Guam AP will meet on Saturday, August 29, 2020, from 9 a.m. to 11 a.m.; and the Mariana Archipelago FEP–CNMI AP will meet on Saturday, September 5, 2020, from 9 a.m. to 11 a.m. All times listed are local island times. For specific times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Each of the meetings will be held by web conference. Audio and visual portions for all of the web conferences can be accessed at: *https://wprfmc.webex.com/join/info.wpcouncilnoaa.gov.* Web conference access information will also be posted on the Council's website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. Information on how to provide public comment will be posted on the Council's website at *www.wpcouncil.org.* The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the American Samoa FEP AP Meeting

Wednesday, August 26, 2020, 5 p.m.–7 p.m.

1. Welcome and Introductions
2. Review of the last AP meeting and recommendations
3. Council Issues
   - A. Development of an Offshore Energy Policy for the Western Pacific Region
   - B. Pacific Remote Island Area (PRIA) Marine Conservation Plan (MCP)-PRIA Objectives and Activities
   - C. Bottomfish Fishery Outreach and Data Collection
   - D. Considerations for Developing Reasonable and Prudent Measures (RPMs) and/or Reasonable and Prudent Alternatives (RPAs) for the American Samoa Longline Fishery
   - E. Mandatory Electronic Reporting in the Hawaii and American Samoa Longline Fisheries
   - F. Council Response to Executive Orders on Promoting American Seafood Competitiveness (E.O. 13921) and Regulatory Relief (E.O. 13924)
4. American Samoa Reports
5. Report on American Samoa Archipelago FEP AP Plan Activities
6. Island Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Hawaii Archipelago FEP AP Meeting

Thursday, August 27, 2020, 9 a.m.–11 a.m.

1. Welcome and Introductions
2. Review of the last AP meeting and recommendations
3. Council Issues
   - A. Development of an Offshore Energy Policy for the Western Pacific Region
   - B. PRIA MCP–PRIA Objectives and Activities
   - C. Options for Mandatory Permitting and Reporting in the Hawaii Small-boat Fishery
   - D. Annual Catch Limits for Hawaii Uku Fishery
   - E. Mandatory Electronic Reporting in the Hawaii and American Samoa Longline Fisheries
   - F. Council Response to Executive Orders on Promoting American Seafood Competitiveness (E.O. 13921) and Regulatory Relief (E.O. 13924)
4. Hawaii Reports
5. Report on Hawaii Archipelago FEP AP Plan Activities
6. Island Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Mariana Archipelago FEP-Guam AP Meeting

Saturday, August 29, 2020, 9 a.m.–11 a.m.

1. Welcome and Introductions
2. Review of the last AP meeting and recommendations
3. Council Issues
   - A. Development of an Offshore Energy

Policy for the Western Pacific Region
B. PRIA MCP–PRIA Objectives and Activities
C. Bottomfish Fishery Outreach and Data Collection
D. Council Response to Executive Orders on Promoting American Seafood Competitiveness (E.O. 13921) and Regulatory Relief (E.O. 13924)
4. Guam Reports
5. Report on Mariana Archipelago FEP Advisory Panel Plan Activities
6. Island Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Schedule and Agenda for the Mariana Archipelago FEP–CNMI AP Meeting

Saturday, September 5, 2020, 9 a.m.–11 a.m.

1. Welcome and Introductions
2. Review of the last AP meeting and recommendations
3. Council Issues
A. Development of an Offshore Energy Policy for the Western Pacific Region
B. PRIA MCP–PRIA Objectives and Activities
C. Bottomfish Fishery Outreach and Data Collection
D. Council Response to Executive Orders on Promoting American Seafood Competitiveness (E.O. 13921) and Regulatory Relief (E.O. 13924)
4. CNMI Reports
5. Report on Mariana Archipelago FEP AP Plan Activities
6. Island Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 7, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–17643 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA354]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of the Scientific and Statistical Committee (SSC) Ecopath Model Review Workgroup.

DATES: The SSC Ecopath Model Review Workgroup meeting will be conducted via webinar on Thursday, August 27, 2020, from 2 p.m. to 4 p.m.

ADDRESSES:

Meeting address: The meeting will be held via webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The SSC Ecopath Model Review Workgroup meeting is open to the public and will be available via webinar as it occurs. Registration is required. Webinar registration information and other meeting materials will be posted to the Council's website at: *https://safmc.net/safmc-meetings/other-meetings/* as it becomes available.

During the meeting, the Workgroup will be provided a more detailed update on Ecopath model refinement and analyses, discuss model review timing and process, vulnerability analyses, Terms of References responses, and recommendations for SSC consideration.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 7, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–17640 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA336]

Atlantic Highly Migratory Species; Meeting of the Atlantic Highly Migratory Species Advisory Panel

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

ACTION: Notice of public webinar/conference call.

SUMMARY: NMFS will hold a 2-day Atlantic Highly Migratory Species (HMS) Advisory Panel (AP) meeting via webinar in September 2020. The intent of the meeting is to consider options for the conservation and management of Atlantic HMS. The meeting is open to the public.

DATES: The AP meeting and webinar will be held from 8:45 a.m. to 3:30 p.m. on Wednesday, September 9, 2020, and from 8:45 a.m. to 3:30 p.m. on Thursday, September 10, 2020.

ADDRESSES: The meeting on Wednesday, September 9, and Thursday, September 10, will be accessible via conference call and webinar. Conference call and webinar access information are available at: *https://www.fisheries.noaa.gov/event/september-2020-hms-advisory-panel-meeting.*

Participants are strongly encouraged to log/dial in 15 minutes prior to the meeting. NMFS will show the presentations via webinar and allow public comment during identified times on the agenda.

FOR FURTHER INFORMATION CONTACT: Peter Cooper at (301) 427–8503.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* as amended by the Sustainable Fisheries Act, Public Law 104–297, provided for the establishment of an AP to assist in the collection and evaluation of information relevant to the development of any FMP or FMP amendment for Atlantic HMS. NMFS consults with and considers the comments and views of AP members when preparing and implementing FMPs or FMP amendments for Atlantic

tunas, swordfish, billfish, and sharks. The AP has previously consulted with NMFS on all Atlantic HMS FMPs and FMP amendments since the inception of the AP in 1998.

The intent of this meeting is to consider alternatives for the conservation and management of all Atlantic tunas, swordfish, billfish, and shark fisheries. We anticipate discussing:

- Draft Amendment 12, which would update the 2006 Consolidated HMS FMP using revised National Standard guidelines;
- Updates on Atlantic shark fisheries and Amendment 14;
- Updates on the bluefin tuna fishery and Amendment 13 (bluefin tuna); and
- Updates on ecosystem modeling in Atlantic HMS fisheries.

We also anticipate inviting other NMFS offices and the United States Coast Guard, if available, to provide updates on their activities relevant to HMS fisheries.

Additional information on the meeting and a copy of the draft agenda will be posted prior to the meeting at: *https://www.fisheries.noaa.gov/event/september-2020-hms-advisory-panel-meeting.*

Dated: August 7, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–17636 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA366]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Herring Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, August 27, 2020 at 9.30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5718649445112607758.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review results of the 2020 management track assessment for Atlantic herring. They will also continue development of Framework 8 to the Atlantic Herring Fishery Management Plan and review preliminary analyses. Framework 8 is considering fishery specifications for fishing years 2021–23 and adjusting measures in the herring plan that potentially inhibit the mackerel fishery from achieving optimum yield. Other business will be discussed as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: August 7, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–17641 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA367]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public hearing.

SUMMARY: The New England Fishery Management Council is convening a public hearing of Draft Amendment 23 to Northeast Multispecies Fishery Management Plan to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This hearing may be held either in-person as an outdoor gathering or via webinar. Details of the hearing will be provided on the Council's website at *https://www.nefmc.org/calendar/aug-26-2020-public-hearing-groundfish-amendment-23.* A summary of all comments received will be provided to the full Council.

DATES: This hearing will be held on Wednesday, August 26, 2020, between 3 p.m.–8 p.m.

ADDRESSES: This hearing may be held either in-person as an outdoor gathering in the Greater Boston area or via webinar. The decision to hold the hearing as an outdoor in-person gathering will be based on COVID–19 pandemic guidance as determined by the Commonwealth of Massachusetts and other factors as determined by the Executive Director in consultation with the Council Chair.

Meeting addresses: The meeting will be held via webinar or in-person as an outdoor gathering. Should the hearing be planned as in-person, details on the location, as well as meeting guidelines and public safety requirements, will be provided on the Council's website. Because of state-mandated limits on the size of outdoor gatherings, in-person meeting attendees may be asked to register in advance and may be assigned to a specific time slot. If a planned in-person meeting has to be cancelled due to adverse weather or other conditions, a webinar hearing will be held in its place.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: *Public comments:* The public comment deadline is August 31, 2020. Mail written comments to Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill #2, Newburyport, MA 01950. Mark the outside of the envelope ''DEIS for Amendment 23 to the Northeast Multispecies FMP''. Comments may also be sent via fax to 978–465–3116 or submitted via email to *comments@nefmc.org* with ''DEIS for Amendment 23 to the Northeast Multispecies FMP'' in the subject line.

Agenda

Council staff will brief the public on Draft Amendment 23 before receiving comments on the amendment. The hearing will begin promptly at the time indicated above. If all attendees who wish to do so have provided their comments prior to the end time indicated, the hearing may conclude early. To the extent possible, the Council may extend hearings beyond the end time indicated above to accommodate all attendees who wish to speak.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: August 7, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–17642 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA375]

Western Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a virtual Fishers Forum and Public Meeting to review the Hawaii Small-boat Fishery. The Council will solicit comments on removing existing fishery closures and options for amending the Hawaii Archipelago Fishery Ecosystem Plan (FEP) and Pacific Pelagics FEP to require mandatory federal fishing permits and associated reporting requirements for the small-boat fishery in the Exclusive Economic Zone around Hawaii.

DATES: The public meeting will be held on Thursday, August 27, 2020, from 6 p.m. to 8 p.m. For specific times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Each of the meetings will be held by web conference. Audio and visual portions for all of the web conferences can be accessed at: *https://wprfmc.webex.com/wprfmc/onstage/g.php?MTID=e16a71e34d5b1ce0d42be73287949fbc2.* Web conference access information will also be posted on the Council's website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. Information on how to provide public comment will be posted on the Council's website at *www.wpcouncil.org.* The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the Virtual Fishers Forum and Hawaii Small-Boat Fishery Public Meeting

Thursday, August 27, 2020, 6 p.m.–8 p.m.

1. Welcome and Introductions
2. Presentations on Fishers as Scientists
   A. Fish Tagging in the Hawaiian Islands
   B. Biosampling of Coral Reef Fish in Hawaii
3. Review of the Hawaii Small-boat Fishery
   A. Revisiting the Federal Fishery Closures Around Hawaii
   B. Options for Mandatory Permitting and Reporting of the Hawaii Small-boat Fisheries
4. Public Comment and Discussion

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 7, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–17644 Filed 8–11–20; 8:45 am]

BILLING CODE 3510–22–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NCCC Team Leader Application; Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled NCCC Team Leader Application for review and approval in accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by September 11, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable

supporting documentation, may be obtained by calling the Corporation for National and Community Service, Gary Crosson, at 202–606–6688 or by email to *GCrosson@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on March 25, 2020 at 16930. This comment period ended May, 26, 2020. No public comments were received in response to this Notice.

Title of Collection: NCCC Team Leader Application.

OMB Control Number: 3045–0005.

Type of Review: Renewal.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 800.

Total Estimated Number of Annual Burden Hours: 1,600.

Abstract: The NCCC Team Leader application, which is available electronically for all applicants, provides information CNCS uses to select Team Leaders for AmeriCorps National Civilian Community Corps (NCCC). CNCS seeks to renew the current information collection. The revisions are intended to allow us to ask more specific questions about the difficulites of serving in the NCCC program and if the applicant is ready for those challenges. The revisions will also allow applicants to provide explantations when they answer ''No'' or ''Maybe'' to one of the seventeen ''Yes,'' ''No,'' or ''Maybe'' questions we ask. The information collection will otherwise be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on 11/30/2020.

Dated: August 3, 2020.

Jacob Sgambati,

Acting Deputy Director, AmeriCorps NCCC.

[FR Doc. 2020–17656 Filed 8–11–20; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF EDUCATION

Accrediting Agencies Currently Undergoing Review for the Purposes of Recognition by the U.S. Secretary of Education

AGENCY: Accreditation Group, Office of Postsecondary Education, Department of Education.

ACTION: Call for written third-party comments.

SUMMARY: This notice provides information to members of the public on submitting written comments for accrediting agencies currently undergoing review for purposes of recognition by the Secretary of Education.

FOR FURTHER INFORMATION CONTACT: Herman Bounds, Director, Accreditation Group, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, Room 270–01, Washington, DC 20202, telephone: (202) 453–7615, or email: *herman.bounds@ed.gov.*

SUPPLEMENTARY INFORMATION: This request for written third-party comments concerning the performance of accrediting agencies under review by the Secretary of Education is required by § 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, and pertains to the summer 2021 meeting of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). The meeting date and location have not been determined, but will be announced in a later **Federal Register** notice. In addition, a later **Federal Register** notice will describe how to register to provide oral comments at the meeting.

Agencies Under Review and Evaluation: The Department requests written comments from the public on the following accrediting agencies, which are currently undergoing review and evaluation by the Accreditation Group, and which will be reviewed at the Summer 2021 NACIQI meeting.

The agencies are listed by the type of application each has submitted. We have also indicated each agency's current scope of recognition. If any agency requests a change to its scope of recognition, we have identified both the current scope of recognition and the requested scope of recognition.

Applications for Renewal of Recognition

1. Accreditation Commission for Acupuncture and Oriental Medicine. Scope of recognition: The accreditation and pre-accreditation (''Candidacy'') throughout the United States of professional non-degree and graduate degree programs, including professional doctoral programs, in the field of acupuncture and/or Oriental medicine, as well as freestanding institutions and colleges of acupuncture and/or Oriental medicine that offer such programs.

2. Accrediting Bureau of Health Education Schools. Scope of recognition: The accreditation of private, postsecondary institutions in the United States offering predominantly* allied health education programs leading to a certificate, diploma, and degrees at the level of the Associate of Applied Science, Associate of Occupational Science, Academic Associate, Baccalaureate and Master's; and the programmatic accreditation of medical assisting, medical laboratory technology, and surgical technology programs, through the Associate degree, including those offered via distance education. The scope extends to the Substantive Change Committee, jointly with the Commission, for decisions on substantive change.

3. Commission on Accrediting of the Association of Theological Schools. Scope of recognition: The accreditation of theological schools and seminaries, as well as schools or programs that are parts of colleges or universities, in the United States, offering post baccalaureate degrees in professional and academic theological education, including delivery via distance education.

4. Accrediting Commission of Career Schools and Colleges. Scope of recognition: The accreditation of postsecondary, non-degree-granting institutions and degree-granting institutions in the United States, including those granting associate, baccalaureate and master's degrees, that are predominantly organized to educate students for occupational, trade and technical careers, and including institutions that offer programs via distance education.

5. Council on Occupational Education. Scope of recognition: The accreditation and preaccreditation (''Candidacy Status'') throughout the United States of postsecondary occupational education institutions

offering non-degree and applied associate degree programs in specific career and technical education fields, including institutions that offer programs via distance education.

6. American Bar Association, Council of the Section of Legal Education and Admissions to the Bar. Scope of recognition: The accreditation throughout the United States of programs in legal education that lead to the first professional degree in law, including those offered via distance education, as well as freestanding law schools offering such programs. This recognition also extends to the Accreditation Committee of the Section of Legal Education (Accreditation Committee) for decisions involving continued accreditation (referred to by the agency as ''approval'') of law schools.

7. American Psychological Association, Commission on Accreditation. Scope of recognition: The accreditation in the United States of doctoral programs in clinical, counseling, school and combined professional-scientific psychology; doctoral internship programs in health service psychology; and postdoctoral residency programs in health service psychology; and the preaccreditation in the United States of doctoral internship programs in health service psychology; and postdoctoral residency programs in health service psychology.

8. American Osteopathic Association, Commission on Osteopathic College Accreditation. Scope of recognition: The accreditation and preaccreditation (''Provisional Accreditation'') throughout the United States of freestanding, public and private non-profit institutions of osteopathic medicine and programs leading to the degree of Doctor of Osteopathy or Doctor of Osteopathic Medicine.

9. Transnational Association of Christian Colleges and Schools, Accreditation Commission. Scope of recognition: The accreditation and preaccreditation (''Candidate'' status) of Christian postsecondary institutions in the United States that offer certificates, diplomas, and associate, baccalaureate, and graduate degrees, including institutions that offer distance education.

10. Accrediting Council for Independent Colleges and Schools. Scope of recognition: The accreditation of private postsecondary institutions offering certificates or diplomas, and postsecondary institutions offering associate, bachelor's, or master's degrees in programs designed to educate students for professional, technical, or occupational careers, including those that offer those programs via distance education.

Submission of Written Comments Regarding a Specific Accrediting Agency Under Review:

Written comments about the recognition of any of the accrediting listed above must be received by September 12, 2020 in the *ThirdPartyComments@ed.gov* mailbox and include the subject line ''Written Comments: (agency name).'' The email must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to an electronic mail message (email) or provided in the body of an email message. Comments about an agency that has submitted a petition for initial recognition, renewal of recognition, or an expansion of scope must relate to the agency's compliance with the Criteria for the Recognition of Accrediting Agencies, which are available at *http://www.ed.gov/admins/finaid/accred/index.html.*

Only written materials submitted by the deadline to the email address listed in this notice, and in accordance with these instructions, become part of the official record concerning agencies scheduled for review and are considered by the Department and NACIQI in their deliberations.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c.

Robert L. King,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2020–17634 Filed 8–11–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0130]

Agency Information Collection Activities; Comment Request; Veterans Upward Bound (VUB) Program Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision to an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 13, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0130. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kenneth Foushee, 202–453–7417.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the

Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Veterans Upward Bound (VUB) Program Annual Performance Report.

OMB Control Number: 1840–0832.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local and Tribal Organizations, Private Sector.

Total Estimated Number of Annual Responses: 62.

Total Estimated Number of Annual Burden Hours: 1,054.

Abstract: Veterans Upward Bound (VUB), one of the U.S. Department of Education's Upward Bound programs, is designed to motivate and assist veterans in developing academic and other requisite skills necessary for acceptance and success in a program of postsecondary education. The program provides assessment and enhancement of basic skills through counseling, mentoring, tutoring and academic instruction in the core subject areas. The primary goal of the program is to increase the rate at which participants enroll in and complete postsecondary education programs.

All Veterans Upward Bound projects must provide instruction in mathematics through pre-calculus, laboratory science, foreign language, composition, and literature. Projects may also provide short-term remedial or refresher courses for veterans who are high school graduates but have delayed pursuing postsecondary education. Projects are also expected to assist veterans in securing support services from other locally available resources such as the U.S. Department of Veterans Affairs, veterans' associations, and other state and local agencies that serve veterans.

The Department's annual performance report (APR) for VUB collects each current grantee's data at the participant level on services and performance over the course of a year. The Department uses the information conveyed in the performance report to assess a grantee's progress in meeting its approved goals and objectives and to evaluate a grantee's prior experience in accordance with the program regulations in 34 CFR 645.32. Grantees' annual performance reports also provide information on the outcomes of projects' work and of the VUB program as a whole. In addition, APR data allows the Department to respond to the reporting requirements of the Government Performance and Results Act.

Dated: August 6, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–17546 Filed 8–11–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0064]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Support Services Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement with change of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before September 11, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Emory Morrison, 202–453–6963.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Support Services Annual Performance Report.

OMB Control Number: 1840–0525.

Type of Review: Reinstatement with change of a previously approved information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 1,069.

Total Estimated Number of Annual Burden Hours: 16,302.

Abstract: Student Support Services (SSS) program grantees must submit the Annual Performance Report (APR) annually. The reports are used to evaluate grantees' performance for substantial progress, respond to the Education Department General Administrative Regulations (GPRA) requirements, and award prior experience points at the end of each project (budget) period. The Department also aggregates the data to provide descriptive information on the projects and to analyze the impact of the SSS program on the academic progress of participating students.

Dated: August 6, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–17545 Filed 8–11–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Accelerated Materials R&D, Testing/Qualification, and Cost-Effective Manufacturing Routes for Harsh Service Environment Materials

AGENCY: Advanced Manufacturing Office, Office of Energy Efficiency and Renewable Energy, Office of Advanced Energy Systems, Office of Fossil Energy, Department of Energy.

ACTION: Request for Information (RFI).

SUMMARY: The Department of Energy (DOE) invites public comment on its Request for Information (RFI) number DE–FOA–0002385 regarding the MATERIALS FOR HARSH SERVICE CONDITIONS R&D. This RFI is sponsored by the Office of Energy Efficiency and Renewable Energy (EERE), Advanced Manufacturing Office (AMO), and the Office of Fossil Energy (FE), Office of Advanced Energy Systems (AES). The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on issues related to challenges and opportunities in various aspects of harsh service environment materials. These include: Accelerated materials research, development, and demonstration (RD&D), testing/qualification methods, and cost-effective manufacturing routes for the development of components, systems, and products exhibiting significant, or step-change improvements over current state-of-the-art in system energy performance under harsh service conditions and extended service lifetimes. This information will be used by AMO and AES to inform strategies in support of energy savings and cost reduction goals, as well as to inform future planning and to possibly make adjustments to their R&D portfolios.

DATES: Responses to the RFI must be received by September 17, 2020.

ADDRESSES: Interested parties are to submit comments electronically to *HarshMaterialsRFI@ee.doe.gov.* Include Harsh Service Materials R&D in the subject of the title. Only electronic responses will be accepted. The complete RFI document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to Nick Lalena, 202–923–5637, or *HarshMaterialsRFI@ee.doe.gov.* Further instructions can be found in the RFI document posted on the EERE Exchange.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on issues related to challenges and opportunities in accelerated materials RD&D, testing/qualification methods, and cost effective manufacturing routes for the development of components, systems, and products exhibiting significant, or step-change improvements over current state-of-the-art in system energy performance under harsh service conditions and extended service lifetimes. Harsh environments include high temperature and corrosive environments, conditions of high mechanical wear/stress/load, thermal cycling and exposure to hydrogen, irradiation, and other embrittlement mechanisms. AMO and AES now seek to gather input from stakeholders on the technical and commercial prospects of novel material development and new manufacturing capabilities including but not limited to the advantages and technical challenges associated with new material breakthroughs, strategies for de-risking the cost and performance of novel materials, and considerations for scale-up of new materials manufacturing methods. AMO and AES seek individual input on high-reaching targets/metrics and identification of key problem sets to be addressed. The intent is to define critical crosscutting problems/barriers whose solutions represent near-term commercially viable paths to obtaining materials that can produce a step change improvement in energy performance under harsh service conditions beyond current state of the art. Specific questions can be found in the RFI. The RFI is available at: *https://eere-exchange.energy.gov/.*

Confidential Business Information

Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on August 06, 2020, by Valri Lightner, Acting Director, Advanced Manufacturing Office, Office of Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 7, 2020.

Treena V. Garrett,

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

[FR Doc. 2020–17605 Filed 8–11–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Hydrogen and Fuel Cell Technologies Office Research and Development Strategy Request for Information

AGENCY: Hydrogen and Fuel Cell Technologies Office (HFTO), Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) number DE–FOA–0002379 regarding the Hydrogen and Fuel Cell Technologies Office Research and Development Strategy. This RFI is issued by the Hydrogen and Fuel Cell Technologies Office (HFTO) within DOE's Office of Energy Efficiency and Renewable Energy (EERE) to understand how hydrogen and fuel cell research priorities and goals can address evolving technology needs and to inform related research, development, and demonstration (RD&D) activities that may be undertaken by DOE. The information being sought under this RFI is intended to assist HFTO in further defining the scope and priorities of its

RD&D initiatives as well as its consortia that were established to address its priorities.

DATES: Responses to the RFI must be received no later than 5:00 p.m. (ET) on September 15, 2020.

ADDRESSES: Interested parties are invited to submit comments using the Online Response Collector found at the specified web link included in the RFI document. Alternatively, responses can be submitted as an attachment to an email addressed to *HFTORFI@ee.doe.gov* with ''HFTO RFI'' in the subject line. Email attachments can be provided as a Microsoft Word (.docx) file or an Adobe PDF (.pdf) file, prepared in accordance with the detailed instructions in the RFI. Documents submitted electronically should clearly indicate which topic areas and specific questions are being addressed, and should be limited to no more than 25 MB in size. The complete RFI [DE–FOA–0002379] document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to *HFTORFI@ee.doe.gov* or to Nancy Garland at 202–586–5673. Further instruction can be found in the RFI document posted on EERE Exchange at *https://eere-exchange.energy.gov/.*

SUPPLEMENTARY INFORMATION: The purpose of the RFI is to obtain public input on HFTO's efforts to accelerate research, development, demonstration, commercialization, and adoption of hydrogen and fuel cell technologies. The information being sought under this RFI is intended to address evolving technologies needs by assisting HFTO in further defining the scope and priorities of its RD&D initiatives and as well as its consortia that were established to address its priorities. More specifically, HFTO request feedback on the following specific areas of interest outlined in the RFI:

1. The H2@Scale Initiative, an initiative supporting innovations to produce, store, transport, and use hydrogen across multiple sectors;
2. the HFTO Strategy and Multiyear Plan;
3. Priority Application Focus Areas, including integrated energy systems, heavy-duty transportation applications, and industrial and chemical applications; and
4. Funding Mechanisms and Opportunities, including lab calls, CRADA, FOAs, and consortia models.

Specific questions can be found in the RFI. The RFI is available at: *https://eere-exchange.energy.gov/.*

Confidential Business Information: Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority: This document of the Department of Energy was signed on August 6, 2020, by Sunita Satyapal, Director, Hydrogen and Fuel Cells Technology Office, Office of Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the U.S. Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 6, 2020.

Treena V. Garrett,

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

[FR Doc. 2020–17544 Filed 8–11–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2586–000]

North Fork Ridge Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced North Fork Ridge Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 25, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17620 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF20–3–000]

Western Area Power Administration; Notice of Filing

Take notice that on July 14, 2020, Western Area Power Administration submitted tariff filing per: UGP_PSMBP–ED_WAPA188–20200710 to be effective 8/2/2019.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 13, 2020.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17617 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2602–000]

Nobles 2 Power Partners, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Nobles 2 Power Partners, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 25, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17619 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2603–000]

Skeleton Creek Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Skeleton Creek Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 25, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17613 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP18–75–006.
Applicants: Algonquin Gas Transmission, LLC.
Description: Compliance filing FRQ Settlement Compliance Filing 3 re Docket RP18–75 to be effective 9/1/2020.
Filed Date: 7/30/20.
Accession Number: 20200730–5015.
Comments Due: 5 p.m. ET 8/11/20.

Docket Numbers: RP20–953–001.
Applicants: Rover Pipeline LLC.
Description: Compliance filing Compliance with RP20–953 Order to be effective 7/12/2020.
Filed Date: 8/4/20.
Accession Number: 20200804–5175.
Comments Due: 5 p.m. ET 8/17/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17611 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC20–87–000.
Applicants: Rippey Wind Energy LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Rippey Wind Energy LLC.
Filed Date: 8/5/20.
Accession Number: 20200805–5085.
Comments Due: 5 p.m. ET 8/26/20.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–225–000.
Applicants: Hardin Solar Holdings LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Hardin Solar Holdings LLC.
Filed Date: 8/5/20.
Accession Number: 20200805–5049.
Comments Due: 5 p.m. ET 8/26/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–2856–001.
Applicants: Birchwood Power Partners, L.P.
Description: Report Filing: Refund Report to be effective N/A.
Filed Date: 8/5/20.
Accession Number: 20200805–5052.
Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2402–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Supplement to Original ISA, SA No. 5682; Queue Nos. AF1–190/AF1–191 to be effective 6/11/2020.
Filed Date: 8/5/20.
Accession Number: 20200805–5103.
Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2607–000.
Applicants: New England Power Company.
Description: Compliance filing: Order No. 864 Compliance Filing Re Seabrook Transmission Support Agreement to be effective 1/27/2020.
Filed Date: 8/4/20.
Accession Number: 20200804–5240.
Comments Due: 5 p.m. ET 8/25/20.
Docket Numbers: ER20–2608–000.
Applicants: Public Service Company of New Hampshire.
Description: Compliance filing: Order No. 864 Compliance Filing, RM19–5 to be effective 1/27/2020.
Filed Date: 8/5/20.
Accession Number: 20200805–5006.
Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2609–000.
Applicants: NSTAR Electric Company.
Description: Compliance filing: Order No. 864 Compliance Filing, RM19–5 to be effective 1/27/2020.
Filed Date: 8/5/20.
Accession Number: 20200805–5008.
Comments Due: 5 p.m. ET 8/26/20.
Docket Numbers: ER20–2610–000.
Applicants: The Connecticut Light and Power Company.
Description: Compliance filing: Order No. 864 Compliance Filing, RM19–5 to be effective 1/27/2020.
Filed Date: 8/5/20.
Accession Number: 20200805–5009.
Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2611–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3723 Southwestern Power Admin & WFEC

Interconnection Agr to be effective 8/1/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5010.

Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2612–000.

Applicants: Hardin Solar Holdings LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/24/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5070.

Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2613–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2020–08–05_SA 3243 Deuel Harvest Wind-OTP 1st Rev GIA (J526) to be effective 7/22/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5072.

Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2614–000.

Applicants: New England Power Company.

Description: Compliance filing: Order No. 864 Compliance Filing Re New England Power AC Support Agreement to be effective 1/27/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5053.

Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2615–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Rate Schedule FERC No. 280 between Tri-State and Wheatland to be effective 8/6/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5130.

Comments Due: 5 p.m. ET 8/26/20.

Docket Numbers: ER20–2616–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: PSCo-TSGT–UPI-Rev. Const, O&M-Fairgrounds SS–318–0.1.0 to be effective 8/6/2020.

Filed Date: 8/5/20.

Accession Number: 20200805–5133.

Comments Due: 5 p.m. ET 8/26/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17612 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2587–000]

Kings Point Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Kings Point Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 25, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17614 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2597–000]

Soldier Creek Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced Soldier Creek Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 25, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: August 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–17616 Filed 8–11–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0235; FRL–10013–37]

1-Bromopropane; Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final Toxic Substances Control Act (TSCA) risk evaluation of 1-Bromopropane (1-BP). The purpose of conducting risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation, without consideration of costs or other nonrisk factors. EPA has determined that specific conditions of use of 1-BP present an unreasonable risk of injury to health. For those conditions of use for which EPA has found an unreasonable risk, EPA must take regulatory action to address that unreasonable risk through risk management measures enumerated in TSCA. EPA has also determined that specific conditions of use do not present unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found no unreasonable risk to health or the environment, the Agency's determination is a final Agency action and is issued via order in the risk evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0235, is available online at *http://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Public Reading Room is closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Dr. Stan Barone, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1169; email address: *barone.stan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be interested in risk evaluations of chemical substances under TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in this final risk evaluation, the EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.'' 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k). TSCA section 6(i) directs that a determination of ''no unreasonable risk''

shall be issued by order and considered to be a final Agency action, while a determination of ''unreasonable risk'' is not considered to be a final Agency action. 15 U.S.C. 2605(i).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i)–(ii) and (iv)–(v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process be completed within a specified timeframe and provide an opportunity for public comment on a draft risk evaluation prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4).

Subsection 5.4.1 of the final risk evaluation for 1-BP constitutes the order required under TSCA section 6(i)(1), and the ''no unreasonable risk'' determinations in that subsection are considered to be a final Agency action effective on the date of issuance of the order. In conducting risk evaluations, ''EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation . . .'' 40 CFR 702.47. Under EPA's implementing regulations, ''[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.'' 40 CFR 702.49(d). For purposes of TSCA section 19(a)(1)(A), the date of issuance of the section 6(i)(1) order for 1-BP shall be at 1:00 p.m. Eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when this notice is published in the **Federal Register**, which is in accordance with 40 CFR 23.5.

C. What action is EPA taking?

EPA is announcing the availability of the risk evaluation of the chemical substance identified in Unit II. In this risk evaluation EPA has made unreasonable risk determinations on some of the conditions of use within the scope of the risk evaluation for this chemical. For those conditions of use for which EPA has found an unreasonable risk of injury to health or the environment, EPA must take regulatory action to address those risks through risk management measures enumerated in 15 U.S.C. 2605(a).

EPA is also announcing the availability of the information required to be provided publicly with each risk evaluation, which is available online at *http://www.regulations.gov* in the dockets identified. 40 CFR 702.51. Specifically, EPA has provided:

- The scope document and problem formulation (in Docket ID No. EPA–HQ–OPPT–2016–0741);
- Draft risk evaluation, and final risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0235);
- All notices, determinations, findings, consent agreements, and orders (in Docket ID No. EPA–HQ–OPPT–2019–0235);
- Any information required to be provided to the Agency under 15 U.S.C. 2603 (in Docket ID No. EPA–HQ–OPPT–2016–0741 and Docket ID No. EPA–HQ–OPPT–2019–0235);
- A nontechnical summary of the risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0235);
- A list of the studies, with the results of the studies, considered in carrying out each risk evaluation (Risk Evaluation for 1-Bromopropane in Docket ID No. EPA–HQ–OPPT–2019–0235);
- The final peer review report, including the response to peer review and public comments received during peer review (in Docket ID No. EPA–HQ–OPPT–2019–0235); and
- Response to public comments received on the draft scope and the draft risk evaluation (in Docket ID No. EPA–HQ–OPPT–2019–0235).

II. TSCA Risk Evaluation

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL–9956–47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at *http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca.* As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL–9964–38), the specific regulatory process set out in 40 CFR part 702, subpart B is being followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

Prior to the publication of this final risk evaluation, a draft risk evaluation was subject to peer review and public comment. EPA reviewed the report from the peer review committee and public comments and has amended the risk evaluation in response to these comments as appropriate. The public comments, peer review report, and EPA's response to comments is in Docket ID No. EPA–HQ–OPPT–2019–0235. Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA's documents and the public comments are in Docket ID No. EPA–HQ–OPPT–2016–0741. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk

evaluation for this chemical is at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-1-bromopropane-1-bp.*

B. What is 1-Bromopropane?

1-BP, also known as n-propyl bromide, is a volatile chemical used as a solvent for cleaning and degreasing (including vapor degreasing, cold cleaning, and aerosol degreasing). Other uses for 1-BP are for consumer and commercial products as adhesives and sealants, in furniture care products, in dry cleaning, spot cleaning and other liquid, spray, and aerosol cleaners, and in automotive care products. Information from the 2016 Chemical Data Reporting (CDR) for 1-BP indicates the reported production volume is between 10 million and 26 million lbs/year (manufacture and import).

Authority: 15 U.S.C. 2601 *et seq.*

Andrew Wheeler,

Administrator.

[FR Doc. 2020–17610 Filed 8–11–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 16990]

Deletion of Items From August 6, 2020 Open Meeting

August 5, 2020.

The following items have been adopted by the Commission and deleted from the list of items scheduled for consideration at the Thursday, August 6, 2020, Open Meeting. The items were previously listed in the Commission's Notice of Thursday, July 30, 2020.

Item No.	Bureau	Subject
3	MEDIA	*Title:* Common Antenna Siting Rules (MB Docket No. 19–282); Modernization of Media Regulation Initiative (MB Docket No. 17–105). *Summary:* The Commission will consider a Report and Order that would eliminate the common antenna siting rules for FM and TV broadcaster applicants and licensees.
4	CONSUMER & GOVERNMENTAL AFFAIRS.	*Title:* Telecommunications Relay Service (CG Docket No. 03–123). *Summary:* The Commission will consider a Report and Order to repeal certain TRS rules that are no longer needed in light of changes in technology and voice communications services.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2020–17565 Filed 8–11–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 20–12]

Nnabugwu Chinedu Andrew, Avers Logistics Ltd., and CJ Deluz Nigeria Ltd., Complainants v. Marine Transport Logistics, Inc., Alla Solovyeva, and Raya Bakhirev, Respondents; Filing of Complaint and Assignment

Served: August 6, 2020.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Nnabugwu Chinedu Andrew, Avers Logistics Ltd., and CJ Deluz Nigeria Ltd., hereinafter ''Complainants'', against Marine Transport Logistics, Inc., Alla Solovyeva, and Raya Bakhirev, hereinafter ''Respondents''. Complainants state they ''are and were foreign buyers of automobiles and were located in the State of Lagos, Federal Republic of Nigeria.'' Complainant states that Respondent Marine Transport Logistics, Inc. ''is and was an international shipping company, providing freight forwarding and logistics services to customers on a worldwide basis and is principally located in the New York City area.'' Complainants state that Respondent Alla Solovyeva ''is and was an officer of MTL.'' Complainants state that Respondent Raya Bakhirev ''is and was employed by MTL as a General Manager.''

Complainant alleges they hired Respondent Marine Transport Logistics, Inc. ''to ship Complainants' vehicles described herein from a warehouse operated by MTL in the United States to various locations abroad via ocean going vessel.''

Complainant alleges that Respondents violated 46 U.S.C. 41102(b), 41102(c), 40102(6)(A)(ii), 40901(a), and 41104. Complainant seeks $172,852.00 in reparations and other relief.

The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/20-12/.*

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by August 6, 2021, and the final decision of the Commission shall be issued by February 23, 2022.

Rachel Dickon,

Secretary.

[FR Doc. 2020–17655 Filed 8–11–20; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551–0001, not later than August 27, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *The Williams Family Goose River Trust, James L. Williams III, as sole trustee, both of Casselton, North Dakota;* to join the Williams Family Group, a group acting in concert, and to acquire voting shares of Goose River Holding Company, and thereby indirectly acquire shares of The Goose River Bank, both of Mayville, North Dakota.

Board of Governors of the Federal Reserve System, August 7, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–17630 Filed 8–11–20; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice MV–2020–03; Docket No. 2020–0002; Sequence No. 29]

Notice of Date Change for GSA Virtual Webinar regarding GSA's Implementation of Section 889 of the FY 2019 National Defense Authorization Act (NDAA)

AGENCY: Office of Governmentwide Policy (OGP), General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: The General Services Administration (GSA) previously announced in its July 22, 2020 **Federal Register** notice that it planned to hold a live and recorded virtual webinar on August 12, 2020. That virtual webinar date has been changed to September 10, 2020.

DATES: Thursday, September 10, 2020, at 1:00 p.m. Eastern Standard Time (EST).

ADDRESSES: The webinar will be held virtually and the call-in information will be made available to registrants. Industry partners wishing to virtually attend must register at: *https://gsa.zoomgov.com/webinar/register/WN_hQ6tHTRDR-mMNnRRxJy22Q.* Members of the press, in addition to registering for this event, must also RSVP to *press@gsa.gov* by Tuesday, September 8, 2020.

FOR FURTHER INFORMATION CONTACT: Patricia Richardson at *patricia.m.richardson@gsa.gov* or Maria Swaby at 202–208–0291.

Authority: National Defense Authorization Act (NDAA) for Fiscal Year 2019, Title VII, Section 889.

Maria Swaby,

GSA Procurement Ombudsman, General Services Administration.

[FR Doc. 2020–17606 Filed 8–11–20; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0092; NIOSH 278]

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following virtual meeting of the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH). This meeting is open to the public via webcast and by teleconference. Time will be available for public comment.

DATES: The meeting will be held on September 29, 2020, from 11 a.m.–4:15 p.m., EDT.

If you wish to attend by webcast or teleconference, please register at the NIOSH website *http://www.cdc.gov/niosh/bsc/* or call (404–498–2581) no later than September 22, 2020.

Written comments received by September 22, 2020 will be provided to the BSC prior to the meeting. Docket number CDC–2020–0092; NIOSH–278 will close September 29, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0092; NIOSH–278 by mail. CDC does not accept comments by email.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket number CDC–2020–0092; NIOSH–278, c/o Sherri Diana, NIOSH Docket Office, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226.

Instructions: All submissions received must include the Agency name and Docket Number. Written public comments received by September 22, 2020 will be provided to the BSC prior to the meeting. Docket number CDC–2020–0092; NIOSH–278 will close September 29, 2020.

FOR FURTHER INFORMATION CONTACT: Emily J.K. Novicki, M.A., M.P.H., Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Ave., MS V24–4, Atlanta, GA 30329, telephone (404) 498–2581, or email at *enovicki@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters To Be Considered: The agenda for the meeting addresses occupational safety and health issues related to: Occupational Data for Health: Progress towards incorporating occupational information in electronic health records and health IT systems; Health Equity and the Paradigm Shift in Occupational Safety and Health; and Evaluation capacity building, a gateway to NIOSH's future impact. An agenda is also posted on the NIOSH website (*http://www.cdc.gov/niosh/bsc/*).

Meeting Information: Adobe Connect webcast will be available at *https://odniosh.adobeconnect.com/nioshbsc/,* and teleconference is available toll-free at (855) 644–0229, Participant Pass Code 9777483. This meeting is open to the public, limited only by the number of Adobe license seats available, which is 100.

Public Participation

Comments received are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other

information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Oral Public Comment: The public is welcome to participate during the public comment period, from 1:30 p.m. to 1:45 p.m., EDT, September 29, 2020. Please note that the public comment period ends at the time indicated above. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Members of the public who wish to address the NIOSH BSC are requested to contact the Executive Secretary for scheduling purposes (see **FOR FUTHER INFORMATION** above).

Written Public Comment: Written comments will also be accepted from those unable to attend the public session per the instructions provided in the address section above. Written comments received in advance of the meeting will be included in the official record of the meeting. Written comments received by September 22, 2020 will be provided to the BSC prior to the meeting. Docket number CDC–2020–0092; NIOSH–278 will close September 29, 2020.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–17552 Filed 8–11–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9125–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2020

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786–1864
II. Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III. CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI. Collections of Information	William Parham	(410) 786–4669
VII. Medicare–Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX. Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI. National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
XIII. Medicare–Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 17, 2020.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 9, 2019 (84 FR 39323), November 6, 2019 (84 FR 59815), February 13, 2020 (85 FR 8282), and April 24, 2020 (85 FR 23030. We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2020)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM), use (CMS-Pub. 100-03) Transmittal No. 10073.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
10050	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10133	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Medicare Benefit Policy (CMS-Pub. 100-02)	
	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
10073	National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM)
10128	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture ACUPUNCTURE for Chronic Lower Back Pain (cLBP) Acupuncture for Fibromyalgia ACUPUNCTURE FOR OSTEOARTHRITIS
10145	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS) Vagus Nerve Stimulation
10179	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR)
10199	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS) Vagus Nerve Stimulation
Medicare Claims Processing (CMS-Pub. 100-04)	
10026	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10027	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1
10028	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture for Chronic Low Back Pain (cLBP) Claims Processing General Information 32/410/3/Institutional Claims Bill Type and Revenue Coding Information Messaging Common Working File (CWF) Editing
10030	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10031	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10033	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10036	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10037	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10038	Quarterly Update to the Fiscal Year 2020 Inpatient Psychiatric Facilities Pricer
10039	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
10041	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10042	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Schedule and Laboratory Services Subject to Reasonable Charge Payment
10044	Claim Status Category and Claim Status Codes Update
10045	Claim Status Category and Claim Status Codes Update
10046	April 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10048	New Waived Tests
10052	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10053	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1
10054	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10058	July 2020 Quarterly Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2020 Pricer
10059	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2020 - Recurring July File Update
10060	Quarterly Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2020 Pricer
10064	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Code from Council for Affordable Quality Healthcare (CAQH) CORE
10067	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10069	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10070	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10071	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan National Coverage Determination (NCDs) services that are considered a Significant cost for Medicare Advantage Institutional Billing for National Coverage Determination (NCDs) Services that are considered a significant cost for Medicare Advantage Services Identified as having Significant Cost for Medicare Advantage
10072	Removal of Signature Line from Appeals Page of the Medicare Summary Notice (MSN) and MSN Envelope Correction Specifications for Section 4 (Last Page): Denials and Appeals
10073	National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM) Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements
10074	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10075	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10079	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10081	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10082	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10084	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10085	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10086	New Codes for Therapist Assistants Providing Maintenance Programs in the Home Health Setting Adjustments of Episode Payment - Low Utilization Payment Adjustments (LUPAs) Adjustments of Episode Payment - Early or Later Episodes Adjustments of Episode Payment – Validation of HIPPS Codes Glossary and Acronym List HH PPS Claim
10087	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10088	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10090	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10093	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10096	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10097	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10098	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
10107	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10120	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2020 Update
10121	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
10122	July 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10123	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10124	New Physician Specialty Code for Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD) and a New Supplier Specialty Code for Home Infusion Therapy Services
10125	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10126	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10128	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP) Acupuncture for Chronic Low Back Pain (cLBP Claims Processing General Information Institutional Claims Bill Type and Revenue Coding Information Messaging Common Working File (CWF) Editing
10129	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10135	Manual Update to Pub. 100-04, Chapter 38, to Remove Identification of Items or Services Related to the 2010 Oil Spill in the Gulf of Mexico Section
10136	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10137	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2020
10140	Updates in the Fiscal Intermediary Shared System (FISS) Inpatient Inputs/Outputs to PRICER Input/Output Record Layout Provider Specific Files (PSF)
10142	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10148	Claim Status Category Codes and Claim Status Codes Update
10149	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10150	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
10151	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
10152	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10153	October 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10154	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
10165	July 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.2
10166	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10167	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2020
10168	July Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10173	Internet Only Manual Update, Pub. 100-04, Chapter 11 Notice of Termination/Revocation (NOTR) Data Required on the Institutional Claim to A/B MAC (HHH) Processing Professional Claims for Hospice Beneficiaries

10174	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10175	Instructions for Downloading the Medicare ZIP Code Files for October 2020
10176	Quarterly Update to Home Health (HH) Grouper
10177	Annual (2021) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
10179	Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR) Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012 Coding Requirements for TAVR Services Furnished on or After January 1, 2013 Claims Processing Requirements for TAVR Services on Professional Claims
10180	Removal of Signature Line from Appeals Page of the Medicare Summary Notice (MSN) and MSN Envelope Correction Specifications for Section 4 (Last Page): Denials and Appeals
10183	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10186	Updates to Chapter 1, Payer Only Codes in the Medicare Claims Processing Manual
10187	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10188	July 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10189	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 26.3, Effective October 1, 2020
10191	Quarterly Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2020 Pricer
10192	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10196	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Secondary Payer (CMS-Pub. 100-05)	
10040	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10101	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10147	Update the International Classification of Diseases, Tenth Revision (ICD- 10) 2021 Tables in the Common Working File (CWF) for Purposes of Processing Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records and Claims
Medicare Financial Management (CMS-Pub. 100-06)	
10035	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10049	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2020
10124	New Physician Specialty Code for Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD) and a New Supplier Specialty Code for Home Infusion Therapy Services Claims Processing Timeliness - All Claims Part E - Interest Payment Data Classification of Claims for Counting Physician/Limited License Physician Specialty Codes Non-Physician Practitioner/Supplier Specialty Codes Exhibit
10164	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare State Operations Manual (CMS-Pub. 100-07)	
201	State Operations Manual (SOM) Chapter 2, The Certification Process
202	State Operations Manual (SOM) Chapter 3, Additional Program Activities
Medicare Program Integrity (CMS-Pub. 100-08)	
10047	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10056	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10057	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10062	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10063	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10099	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10100	Revision to Language in Chapter 3, Section 3.7.5 (Corrective Action Reporting Requirements) of Publication (Pub.) 100-08
10111	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10117	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10130	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10131	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10132	Revising Subsection 3.2.5, Targeted Probe and Educate (TPE), in Chapter 3 of Publication (Pub.) 100-08
10134	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10138	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment)
10146	Implementation of Provider Enrollment Provisions in CMS-6058-FC – Phase 1 – Continued Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08
10156	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10157	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10159	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

10169	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10171	Updates to Durable Medical Equipment, Prosthetics, Orthotics & Supplies
10182	Update to Chapter 10 of Publication (Pub.) 100-08 - Model Letter Templates Model Letters Approval Letters DME Approval Letter Templates Part A/B Certified Provider Approval Letter Templates Part B Non-Certified Supplier Approval Letter Templates
10184	Updates to Chapters 4, 6, and 8 of Publication (Pub.) 100-0
10190	Suppliers Documentation for DMEPOS Repair Claims Suppliers Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RADs) Evidence of Medical Necessity Evidence of Medical Necessity for the Oxygen Claims Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims Period of Medical Necessity - Home Dialysis Equipment Safeguards in Making Monthly Payments Reserved for Future Use Pick-up Slips Incurred Expenses for DMEPOS Reserved for Future Use Definitions of Customized DMEPOS - Advance Determination of Medical Coverage (ADMC) of Customized DMEPOS Items Eligible for ADMC Instructions for Submitting ADMC Requests Instructions for Processing ADMC Requests Affirmative ADMC Decisions Negative ADMC Decisions DME MAC Tracking Recent Final Rule CMS-1713-F
10194	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10197	Publication (Pub.) 100-08 Chapter 3 Updates to Section 3.2.3.2 (Timeframes for Submission) and Section 3.2.3.8 (No Response or Insufficient Response to Additional Documentation Requests (ADRs) Timeframes for Submission No Response or Insufficient Response to Additional Documentation Requests
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
10144	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10195	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None

Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
10185	Update to Chapter 1 of Publication (Pub.) 100-15 Fraud Referrals
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
10051	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10113	Remove/Archive Demonstration Code 58 - Inactive Medicare Demonstration Projects within the Multi Carrier System (MCS) and Common Working File (CWF) System
10114	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10127	Value-Based Insurance Design (VBID) Model – Implementation
10141	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 1: Provider, Beneficiary and Procedure Code Files to Support Model Implementation
10170	Value-Based Insurance Design (VBID) Model – Implementation
10181	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
10023	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10024	Second Update to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
10025	Update to the Home Health Grouper for New Diagnosis Codes for Vaping Related Disorder and COVID-19.
10029	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder and 2019 Novel Coronavirus (COVID-19)
10032	User CR: ViPS Medicare System (VMS) Report Daily Edit Receipts
10034	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
10043	Implementation of Additional Requirement to add Healthcare Common Procedure Coding System (HCPC) and Current Procedural Terminology (CPT) - HCPC/CPT as Paired Items of Service for Prior Authorization and Medicare Claims Processing for Part A and Home Health and Hospice
10055	Implementation of the Award for the Jurisdiction 5 Part A and Part B Medicare Administrative Contractor (J-5 A/B MAC)
10061	Provider Education for Required Prior Authorization (PA) of Hospital Outpatient Department (OPD) Services
10065	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
10066	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code U0002 and 87635
10068	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity

	of Instructions
10076	COBOL Version 6.2 Upgrade - Additional Analysis and Phase I Implementation
10077	Coding Support for Secure Destruction Program Implemented in Change Request (CR)
10078	Additional Coordination of Benefits (COB) Workload Numbers Added to the Medicare Part B Contractor Reporting Operational Workload Data (CROWD) Table for Purposes of Identifying Medicare Secondary Payer (MSP) Part B Recovery Savings for the Benefits Coordination and Recovery Center (BCRC) and the Commercial Repayment Center (CRC) Contractors
10080	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10083	Update to Medicare Shared Savings Program (SSP) Skilled Nursing Facility (SNF) Affiliates' Requirement to Include Demonstration Code 77 on SNF Waiver Claims
10089	Implementation of the Error Scenario for the Document Code File (DCF) and Data Element Format Revisions for Providers Participating in the Electronic Medical Documentation Requests (eMDR) via the Electronic Submission of Medical Documentation (esMD) System
10091	Systematic Updating of the Spanish Medicare Summary Notice (MSN) Short Descriptors
10092	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—October 2020 Update
10094	Implementation for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Saviynt Migration
10095	Updates to Ensure the Original 1-Day and 3-Day Payment Window Edits are Consistent With Current Policy
10102	User Change Request (CR): Fiscal Intermediary Shared System (FISS) – Operator Control File Enhancement for Online Parm Access
10103	Editing Update for Abdominal Aortic Aneurism and Screening Pap Smears and Pelvic Examinations
10104	Expand Retention of Claims History for Outpatient, Part B, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to 5 Years
10105	User CR: ViPS Medicare System (VMS) - Update Waiver of Liability Claim Edits 6142 and 6143
10106	User Change Request (UCR): Implementation Requirements for Analysis UCR 10766 - Reduce Unmailable Medicare Summary Notices (uMSNs) Created in the Fiscal Intermediary Shared System
10108	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10109	Updates to Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) to Correct the Adjustment Process
10110	Implement Error Tracking into the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) Non-RAC Prepayment File Layout
10112	Common Working File (CWF) to Medicare Beneficiary Database (MBD) Extract File Changes to send Hospice DOEBA, DOLBA dates and days used to support HIPAA Eligibility Transaction System (HETS)
10115	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10116	Extension of Payment for Section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
10118	User CR: ViPS Medicare System (VMS) - Contractor Options Screen Contractor Options Screen (VMAP/1/1) Automation
10119	User Change Request (CR): Fiscal Intermediary Shared System (FISS) – Invalid User IDs on the Operator Control File
10139	Therapy Codes Update
10143	Editing Update for Abdominal Aortic Aneurism and Screening Pap Smears and Pelvic Examinations
10155	Provider Education for Required Prior Authorization (PA) of Hospital Outpatient Department (OPD) Services
10158	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10160	Summary of Policies in the Calendar Year (CY) 2020 Medicare Physician Fee Schedule (MPFS) Public Health Emergency (PHE) Interim Final Rules
10161	Therapy Codes Update
10162	COBOL Version 6.2 Upgrade - Additional Analysis and Phase I Implementation
10163	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10172	Medicare Appeals System (MAS) Enhanced Web Services for Part A Medicare Administrative Contractors
10178	New Point of Origin Code for Transfer From a Designated Disaster Alternate Care Site
10193	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--July 2020 Update
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2020)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present

date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs1q20qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2020)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2020)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410 786 7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)	NCD 20.32	10199	06/23/2020	02/15/2019
National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM)	NCD 10.19	10073	05/01/2020	07/02/2019
National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)	NCD 30.3.3	10128	05/18/2020	01/21/2020

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2020)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (April through June 2020)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (April through June 2020)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in

performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
St. John's Regional Medical Center 1600 N. Rose Avenue Oxnard, CA 93030	1073665360	05/19/2020	CA
Tidelands Georgetown Memorial Hospital 606 Back River Road Georgetown, SC 29442 Other Information: P.O. Box 421718	420020	06/09/2020	SC
HCA Houston Healthcare Conroe 504 Medical Center Boulevard Conroe, TX 77304	1962455816	02/10/2020	TX
Monongalia County General Hospital Company 1200 JD Anderson Drive Morgantown, WV 26505 Other Information: d/b/a Mon Health Medical Center	510024	06/23/2020	WV
The following facilities have editorial changes (in bold).			
Baptist Health Regionals (Ft. Smith) **1001 Towson Avenue** **Fort Smith AR 72901-4921**	040055	09/22/2005	AR
Jackson Madison County General **620 Skyline Drive** **Jackson, TN 38301**	440002	08/23/2005	TN
Springhill Medical Center **3719 Dauphine Street** **Mobile, AL 36608**	010144	08/22/2005	AL

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2020)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2020)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2020)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2020)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2020)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities have editorial changes (in bold).				
Morristown Medical Center 100 Madison Avenue Morristown, NJ 07960 Other information: **Joint Commission ID # 5958** **Previous Re-certification Dates:** **06/16/2009; 09/28/2011; 10/31/2013; 11/17/2015; 12/12/2017**	310015	06/16/2009	**01/25/2020**	NJ
Piedmont Hospital, Inc. 1968 Peachtree Rd NW Atlanta, GA 30309 Other information: **Certificate ID # 502231-2020-VAD** **Previous Re-certification Dates: 6/9/2011; 2/8/17**	110083	06/09/2011	**03/19/2020**	GA
FROM: Florida Hospital **TO: Adventist Health System/Sunbelt Inc.** 601 East Rollins Street Orlando, FL 32803 Other information: **Joint Commission ID # 6873** **Previous Re-certification Dates:** **10/24/2012; 10/07/2014; 11/15/2016**	100007	10/24/2012	**01/30/2019**	FL

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602 Other information: **Joint Commission ID # 6086** **Previous Re-Certification Dates:** **05/19/2009; 09/23/2011; 09/06/2013; 09/22/2015; 10/03/2017**	390100	05/19/2009	**02/05/2020**	PA
WellSpan York Hospital 1001 South George Street York, PA 17405 Other information: **Joint Commission ID # 6228** **Previous Re-certification Dates:** **11/19/2013; 12/15/2015; 01/23/2018**	390046	11/19/2013	**03/14/2020**	PA
FROM: Aurora St. Luke's Medical Center of Aurora Health Care Metro, Inc. **TO: Aurora Health Care Metro, Inc.** **Aurora Health Care Metro, Inc.** 2900 West Oklahoma Avenue Milwaukee, WI 53201-2901 Other information: **Joint Commission ID # 7675** **Previous Re-certification Dates:** **02/03/2009; 08/09/2011; 07/17/2013; 07/21/2015; 11/14/2017**	520138	02/03/2009	**02/12/2020**	WI
Lehigh Valley Hospital 1200 S. Cedar Crest Boulevard Allentown, PA 18105 Other information: **Joint Commission ID # 4880** **Previous Re-certification Dates:** **10/29/2013; 11/10/2015; 12/12/2017**	390133	10/29/2013	**03/04/2020**	PA
FROM: CHI St. Vincent Heart Clinic; **TO: St. Vincent Infirmary Medical Center dba CHI St. Vincent** 2 St. Vincent Circle Little Rock, AR 72205 Other information: **Joint Commission ID # 8661** **Previous Re-certification Dates:** **11/21/2017**	040007	11/21/2017	**02/05/2020**	AR
Scott & White Medical Center 2401 South 31st Street Temple, TX 76508 Other information: **Joint Commission ID # 9241** **Previous Re-certification Dates:** **12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017**	45-0054	12/07/2011	**03/05/2020**	TX
Ochsner Medical Center 1516 Jefferson Highway New Orleans, LA 70121 Other information: **Joint Commission ID # 8777** **Previous Re-certification Dates:** **05/28/2009; 11/09/2011; 12/12/2013; 01/05/2016; 12/12/2017**	19-0036	05/28/2009	**03/12/2020**	LA

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Baptist Health Medical Center - Little Rock 9601 Baptist Health Drive Little Rock, AR 72205-7299 Other information: **Joint Commission ID # 8656** **Previous Re-certification Dates:** **11/10/2009; 11/08/2011; 12/11/2013; 01/12/2016; 12/15/2017**	04-0114	11/10/2009	**02/12/2020**	AR
Westchester Health Care Corporation 100 Woods Road Valhalla, NY 10595 Other information: **Joint Commission ID # 2518** **Previous Re-certification Dates:** **11/19/2009; 11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017**	330234	11/19/2009	**03/07/2020**	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2020)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2020)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2020)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2020–17577 Filed 8–11–20; 8:45 am]

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Center for States Evaluation Ancillary Data Collection (0970–0501)

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the collection of information under the Center for States Evaluation Ancillary Data Collection (OMB #0970–0501, expiration date 08/31/2020) without changes.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The Evaluation of the Child Welfare Capacity Building Collaborative, Center for States is sponsored by the Children's Bureau (CB), ACF. The purpose of this evaluation is to respond to a set of cross-cutting evaluation questions posed by CB. This existing information collection is an ancillary part of a larger data collection effort being conducted for the evaluation of the Child Welfare Capacity Building Collaborative (0970–0484 and 0970–0494). This notice details a group of instruments that are specific only to the Center for States. The instruments focus on (1) evaluating an innovative approach to engaging professionals in networking and professional development through virtual conferences, (2) understanding fidelity to and effectiveness of the Center for States' Capacity Building Model, and (3) capturing consistent information during the updated annual assessment process focused on related contextual issues impacting potential service delivery such as implementation of new legislation.

Respondents: Child welfare agency staff and stakeholders who directly receive services.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Child Welfare Virtual Conference:					
Child Welfare Virtual Conference Session Surveys.	450	6	.08	216	72
Child Welfare Virtual Conference Focus Group Guide.	30	1	1	30	10
Child Welfare Virtual Conference Interview Guide.	20	1	.5	10	3
Child Welfare Virtual Conference Registration Form.	1,000	1	.03	30	10
Child Welfare Virtual Conference Exit Survey.	225	1	.16	36	12
Tailored Services Capacity Building Approach:					
Tailored Services Practice Model Survey	130	1	.12	15.6	5
Assessment Observation—Group Debrief	50	1	.25	12.5	4
Service Delivery and Tracking and Adjustment Observation—Group Debrief.	80	1	.25	20	7
Assessment and Service Delivery State Lead Interviews—Supplemental Questions.	30	1	.5	15	5
Assessment questions:					
Annual Assessment Update (8 systematic questions).	54	1	.08	4.32	1
Total					130

Authority: Section 203 of Section II: Adoption Opportunities of the Child Abuse Prevention and Treatment Act (CAPTA) (42 U.S.C. 5113).

John M. Sweet,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–17590 Filed 8–11–20; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1027]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 11, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0188. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280

OMB Control Number 0910–0188—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(e)) (FD&C Act) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 (21 CFR 107.230) requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 (21 CFR 107.240) requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for FDA's written concurrence (§ 107.250 (21 CFR 107.250)). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260 (21 CFR 107.260)). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280 (21 CFR 107.280)).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination, nutritional inadequacy, or is otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

Description of Respondents: Respondents to this collection of information are manufacturers of infant formula who are for-profit businesses in the private sector.

In the **Federal Register** of April 27, 2020 (85 FR 23367), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
107.230; Elements of infant formula recall	2	1	2	4,450	8,900
107.240; Notification requirements	2	1	2	1,482	2,964
107.250; Termination of infant formula recall	2	1	2	120	240
107.260; Revision of an infant formula recall	1	1	1	625	625

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total [2]					12,729

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting and third-party disclosure burden estimates are based on Agency data, which shows that there are six manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there are, on average, approximately two infant formula recalls per year.

Thus, we estimate that two respondents conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because we seldom use this section; therefore, we estimate that there are one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on our experience and information from firms that have conducted recalls. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it takes 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. We estimate that two respondents conduct infant formula recalls under § 107.240 and that it takes a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that two respondents submit recommendations for termination of infant formula recalls under § 107.250 and that it takes a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that one respondent needs to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours. Therefore, the total annual burden hours for reporting is 12,729 hours (8,900 + 2,964 + 240 + 625).

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on our experience with the information collection. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. We estimate that two respondents conduct infant formula recalls under § 107.230 and that it takes a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that one respondent issues additional notifications under § 107.260 and that it takes a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours. The total annual third-party disclosure burden is 125 hours (100 + 25).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 6, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17542 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2966]

Male Breast Cancer: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Male Breast Cancer: Developing Drugs for Treatment.'' This guidance provides recommendations regarding the development and labeling of cancer drugs, including biological products, regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of male patients with breast cancer. Specifically, this guidance recommends the inclusion of male patients in clinical trials of breast cancer drugs and provides recommendations on clinical development when males have either not been included in clinical trials for drugs to treat breast cancer or when inclusion of males in those trials is very limited. The development of drugs for male breast cancer may provide clinical data and additional FDA-approved treatment options to improve the clinical management of breast cancer in male patients. The guidance announced in this notice finalizes the draft guidance of the same title issued on August 27, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on August 12, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–2966 for ''Male Breast Cancer: Developing Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, or phone 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, CDER, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Male Breast Cancer: Developing Drugs for Treatment.'' This guidance provides recommendations for sponsors regarding the development and labeling of cancer drugs and biological products regulated by CDER and CBER for the treatment of male patients with breast cancer. Males have historically been excluded from clinical trials of breast cancer drugs because breast cancer in males is rare. This has resulted in limited FDA-approved treatment options for males. Clinical management of male breast cancer is generally based on experience with and data from females with breast cancer, rather than on data from prospective, randomized clinical trials.

The final guidance recommends sponsors discuss their breast cancer

drug development plan early in development with CDER or CBER, as applicable. The guidance recommends that eligibility criteria for clinical trials of breast cancer drugs allow for inclusion of males. When males have not been included or when inclusion of males is very limited in clinical trials for breast cancer drugs, the guidance includes clinical development recommendations for when no difference in efficacy or safety is anticipated between males and females based on the drug's mechanism of action and for when there is a concern for differential efficacy or safety between males and females.

This guidance finalizes the draft guidance entitled ''Male Breast Cancer: Developing Drugs for Treatment'' issued on August 27, 2019. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the addition of examples of topics for early discussion with FDA and expectations regarding nonclinical studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Male Breast Cancer: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: August 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17575 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Health Workforce Connector, OMB No. 0906–0031—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than October 13, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Health Workforce Connector, OMB No. 0906–0031—Extension.

Abstract: More than just a job search portal, the goal of the Health Workforce Connector is to help connect skilled professionals to communities in need by allowing approved Site Points of Contact (POCs), including National Health Service Corps (NHSC) and Nurse Corps, to post available opportunities and update site profiles. The Health Workforce Connector provides a central platform to connect participants, including those in both the NHSC and Nurse Corps programs, and facilities that are approved for performance of their NHSC or Nurse Corps service obligation. The Health Workforce Connector has become a resource that engages any health care professional or student interested in providing primary care services in underserved communities and with facilities in need of health care providers. The Health Workforce Connector also allows users to create a profile, search for NHSC and Nurse Corps sites, find job and training opportunities, search for other clinicians who are similarly interested in working with underserved populations, and be searchable by Site POCs. Individuals can use the Health Workforce Connector's search capability with Google Maps.

Need and Proposed Use of the Information: Information will be collected from users in the following two ways:

(1) *Account Creation:* Creating an account is optional, but to create an account the user will be required to enter their first name, last name, and email address. Those are the only mandatory fields in the profile account creation process and will be used to send an automated email allowing the user to validate their login credentials. This information will also be used to validate any users who already exist within the Bureau of Health Workforce Management Information Systems Solution (BMISS) database and allow an initial import of existing data at the request of the user.

(2) *Profile Completion:* Users may fill out a profile, but this function will be completely optional and will include fields such as location, discipline, specialty, and languages spoken. The information collected, if 'published' by the user, will allow internal BMISS Site POCs to search for anyone who may be a potential candidate for job opportunities at the site. Users also have the ability to make their profiles searchable by other end users through a security and privacy setting and can make their profiles private at any time. All information collected will be stored within existing secure BMISS databases and will be used internally for report generation on an as-needed basis.

Likely Respondents: Potential users will include individuals searching for a health care job opportunity or an NHSC or Nurse Corps health care facility, and

health care facilities searching for potential candidates to fill open health care job opportunities at their sites.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Account Creation	15,600	1	15,600	.08	1,248
Complete Profile	9,400	1	9,400	1	9,400
Total	[1] 15,600		15,600		10,648

[1] The 9,400 respondents who complete their profiles are a subset of the 15,600 respondents who create accounts.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–17635 Filed 8–11–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Zhiwei Wang, M.D. (Respondent), former postdoctoral fellow, Department of Pathology, Karmanos Cancer Institute, Wayne State University (WSU). Dr. Wang engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants P20 CA101936, P30 CA022453, R01 CA075059, R01 CA083695, R01 CA101870, R01 CA109389, R01CA131151, R01 CA132794, and U19 CA113317. The administrative actions, including debarment for a period of ten (10) years, were implemented beginning on July 21, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Zhiwei Wang, M.D., Wayne State University: Based on the report of an investigation conducted by WSU and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Zhiwei Wang, former postdoctoral fellow, Department of Pathology, Karmanos Cancer Institute, WSU, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P20 CA101936, P30 CA022453, R01 CA075059, R01 CA083695, R01 CA101870, R01 CA109389, R01CA131151, R01 CA132794, and U19 CA113317.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying data that were included in grant applications R01 CA120008, R01 CA131151, and R01 CA131456 submitted to NCI, NIH; his 2006 Ph.D. dissertation (hereafter referred to as the ''Dissertation''); and the following published papers:

- Activated K-Ras and INK4a/Arf deficiency promote aggressiveness of pancreatic cancer by induction of EMT consistent with cancer stem cell phenotype. *J Cell Physiol.* 2013 Mar;228(3):556–62 (hereafter referred to as ''*J Cell Physiol.* 2013''). Erratum in: *J Cell Physiol.* 2014 Aug;229(8):1118. Retraction in: *J Cell Physiol.* 2016 Oct;231(10):2304.
- Activated K-ras and INK4a/Arf deficiency cooperate during the development of pancreatic cancer by activation of Notch and NF-κB signaling pathways. *PLoS One* 2011;6(6):e20537 (hereafter referred to as ''*PLoS One* 2011''). Erratum in: *PLoS One* 2014;9(6):e101032. Retraction in: *PLoS One.* 2018 Oct 2;13(10):e0205289.
- Down-regulation of Notch-1 is associated with Akt and FoxM1 in inducing cell growth inhibition and apoptosis in prostate cancer cells. *J Cell Biochem.* 2011 Jan;112(1):78–88 (hereafter referred to as ''*J Cell Biochem.* 2011''). Retraction in: *J Cell Biochem.* 2016 Aug;117(8):1962.
- Down-regulation of Notch-1 and Jagged-1 inhibits prostate cancer cell growth, migration and invasion, and induces apoptosis via inactivation of Akt, mTOR, and NF-κB signaling pathways. *J Cell Biochem.* 2010 Mar 1;109(4):726–36 (hereafter referred to as ''*J Cell Biochem.* 2010''). Retraction in: *J Cell Biochem.* 2016 Aug;117(8):1960.
- TW–37, a small-molecule inhibitor of Bcl-2, inhibits cell growth and invasion in pancreatic cancer. *Int J Cancer* 2008 Aug 15;123(4):958–66 (hereafter referred to as ''*Int J Cancer* 2008''). Retraction in*: Int J Cancer.* 2016 Nov 1;139(9):2146.
- Induction of growth arrest and apoptosis in human breast cancer cells by 3,3-diindolylmethane is associated with induction and nuclear localization of p27kip. *Mol Cancer Ther.* 2008 Feb;7(2):341–9 (hereafter referred to as ''*Mol Cancer Ther.* 2008'').
- Down-regulation of platelet-derived growth factor-D inhibits cell growth and angiogenesis through inactivation of Notch-1 and nuclear factor-κB signaling. *Cancer Res.* 2007 Dec 1; 67(23):11377–85 (hereafter referred to as ''*Cancer Res.*

2007c''). Retraction in: *Cancer Res.* 2018 Sep 15;78(18):5469.

• Down-regulation of Forkhead Box M1 transcription factor leads to the inhibition of invasion and angiogenesis of pancreatic cancer cells. *Cancer Res.* 2007 Sep 1;67(17):8293–300 (hereafter referred to as ''*Cancer Res.* 2007b''). Retraction in: *Cancer Res.* 2018 Sep 15; 78(18):5470.

• Inhibition of angiogenesis and invasion by 3,3′-diindolylmethane is mediated by the nuclear factor-κB downstream target genes MMP–9 and uPA that regulated bioavailability of vascular endothelial growth factor in prostate cancer. *Cancer Res.* 2007 Apr 1;67(7):3310–9 (hereafter referred to as ''*Cancer Res.* 2007a''). Retraction in: *Cancer Res.* 2018 Sep 15; 78(18):5471.

• Notch-1 down-regulation by curcumin is associated with the inhibition of cell growth and the induction of apoptosis in pancreatic cancer cells. *Cancer* 2006 Jun 1;106(11):2503–13 (hereafter referred to as ''*Cancer* 2006''). Retraction in: *Cancer* 2016 Oct 15;122(20):3247.

• Epidermal growth factor receptor-related protein inhibits cell growth and invasion in pancreatic cancer. *Cancer Res.* 2006 Aug 1;66(15):7653–60 (hereafter referred to as ''*Cancer Res.* 2006b''). Retraction in: *Cancer Res.* 2018 Sep 15;78(18):5474.

• Inhibition of nuclear factor kappaβ activity by genistein is mediated via Notch-1 signaling pathway in pancreatic cancer cells. *Int J Cancer* 2006 Apr 15;118(8):1930–6 (hereafter referred to as ''*Int J Cancer* 2006''). Erratum in: *Int J Cancer* 2014 Apr 15;134(8):E3. Retraction in: *Int J Cancer* 2016 Nov 1;139(9):2145.

• Down-regulation of Notch-1 inhibits invasion by inactivation of nuclear factor-kappaβ, vascular endothelial growth factor, and matrix metalloproteinase-9 in pancreatic cancer cells. *Cancer Res.* 2006 Mar 1;66(5):2778–84 (hereafter referred to as ''*Cancer Res.* 2006a''). Retraction in: *Cancer Res.* 2018 Sep 15;78(18):5476.

• Down-regulation of Notch-1 contributes to cell growth inhibition and apoptosis in pancreatic cancer cells. *Mol Cancer Ther.* 2006 Mar;5(3):483–93 (hereafter referred to as ''*Mol Cancer Ther.* 2006''). Retraction in: *Mol Cancer Ther.* 2018 Oct;17(10):2268.

ORI found by a preponderance of evidence that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating images representing protein expression, invasion and migration assays, and electrophoretic mobility shift assays (EMSA) in experiments designed to identify underlying mechanisms controlling cell proliferation, differentiation, and apoptosis in cancer so that novel targeted therapeutic agents could be identified.

Specifically, Respondent reused and relabeled:

• The same protein bands to represent experimental conditions in:

—Figure 6D (upper panel) in the Dissertation; Figure 1D (upper panel) in *Mol Cancer Ther.* 2006: Down-regulation of Notch-1 expression by siRNA in BxPC–3, HPAC, and PANC–1 cells

—Figure 6D (lower panel) in the Dissertation; Figure 1D (lower panel) in *Mol Cancer Ther.* 2006: Up-regulation of Notch-1 expression by cDNA transfection in BxPC–3, HPAC, and PANC–1 cells

—Figure 8A in *Mol Cancer Ther.* 2006: Down-regulation of Notch-1 expression by genistein and Notch-1 siRNA

—Figure 4 in *Int J Cancer* 2006: Down-regulation of Notch-1 expression by genistein and Notch-1 siRNA

• inhibition of Bcl-X_L (0–72 hours with genistein) in BxPC–3 cells in Figure 20 in the Dissertation, Figure 7B in *Mol Cancer Ther.* 2006, and Figure 3C in *Int J Cancer* 2006 to also represent:

—Inhibition of Bcl-X_L (0–13 uM curcumin) in PANC–1 cells in Figure 3D in *Cancer* 2006

—inhibition of Notch-1 expression (ERRP and Notch-1 siRNA transfection) in BxPC–3 cells in Figure 5A in *Cancer Res.* 2006b

• inhibition of Hes-1 (0–72 hours genistein) in BxPC–3 cells in Figure 7B in *Mol Cancer Ther.* 2006 to also represent:

—Inhibition of Cyclin D1 (0–72 hours with genistein) in BxPC–3 cells in Figure 20 in the Dissertation and Figure 3C in *Int J Cancer* 2006

—inhibition of Cyclin D1 (0–13 uM curcumin in PANC–1 cells) in Figure 3D in *Cancer* 2006

• inhibition of Cyclin D1 (0–72 hours with genistein) in BxPC–3 cells in Figure 7B in *Mol Cancer Ther.* 2006 to also represent inhibition of Hes-1 (0–72 hours with genistein) in BxPC–3 cells in Figure 20 in the Dissertation and Figure 3C in *Int J Cancer* 2006

• expression of Bcl-2 in control and Notch-1 siRNA transfected pancreatic cell lines (BxPC–3, HPAC) in Figure 10 in the Dissertation and Figure 5 in *Mol Cancer Ther.* 2006 to represent expression of Notch-1 in control and PDGF–D siRNA transfected pancreatic cells in Figure 4A in *Cancer Res.* 2007c.

• representing expression of Cyclin D1 and Bcl-X_L in control and Notch-1 siRNA transfected pancreatic cell lines (BxPC–3, HPAC, PANC–1) in Figure 10 in the Dissertation and Figure 5D in *Mol Cancer Ther.* 2006 to represent expression of Hes-1 and Cyclin D1 in control and ERRP-incubated pancreatic cells in Figure 2C in *Cancer Res.* 2006b

• expression of p27 in control and Notch-1 siRNA transfected pancreatic cell lines (HPAC) in Figure 10 in the Dissertation and Figure 5 in *Mol Cancer Ther.* 2006 to represent VEGF protein expression in control and Notch-1 plasmid transfected BxPC–3 cells in Figure 4B in *Cancer Res.* 2006a

• expression of Cyclin D1 in control and Notch-1 siRNA transfected pancreatic cell lines in Figure 10 in the Dissertation and Figure 5 in *Mol Cancer Ther.* 2006 to represent the expression of uPAR genes in control siRNA and FoxM1 siRNA transfected pancreatic cancer cells in Figure 5B in *Cancer Res.* 2007b

• expression of Hes-1 in control and ERRP-incubated pancreatic cancer cells in Figure 2C in *Cancer Res.* 2006b to represent the expression of uPAR genes in control siRNA and FoxM1 siRNA transfected pancreatic cancer cells in Figure 5B in *Cancer Res.* 2007b

• expression of Hes-1 in control and ERRP-incubated pancreatic cells in Figure 2C in *Cancer Res.* 2006b to represent control, TGF-α, and TGF-α+ERRP effects on Notch-1 activation in BxPC–3 cells in Figure 2D in *Cancer Res.* 2006b

• inhibition of Bcl-X_L, Hes-1, and Cyclin D protein expression by genistein in BxPC–3 cells at 0, 24, 48, and 72 hours in three different experiments in Figure 7B in *Mol Cancer Ther.* 2006 to represent the same protein expressions in one experiment in Figure 3C in *Int J Cancer* 2006

• up-regulation of Notch-1 in cDNA-transfected BxPC–3 cells in Figure 5C in *Cancer Res.* 2006b to also show that ERRP inhibits the expression of MMP–9 in Figure 6 in *Cancer Res.* 2006b

• expression of Notch-1 when transfected with Jagged-1 siRNA in PC–3 cells in Figure 5A in *J Cell Biochem.* 2010 to also show the expression of Notch-1 when transfected with Notch-1 siRNA in C4–2B cells in Figure 3A in *J Cell Biochem.* 2011

• expression of Notch-4 in a genetically modified mouse model (KCI) in Figure 1D in *PLoS One* 2011 to also

show the expression of Bcl-2 in the same mouse model in Figure 3A in the same paper
- expression of EZH2 in IC, KC, and KCI transgenic mice to also represent the expression of E-cadherin in the same mouse types in Figure 4B in *J Cell Physiol.* 2013

Respondent reused and relabeled one set of β-actin bands to represent loading controls for the following experiments showing:
- Inhibition of VEGF in Notch-1 siRNA transfected BxPC–3 cells in Figure 16B in the Dissertation
- inhibition of cyclin D_1 in genistein-treated BxPC–3 cells over time in Figure 7B in *Mol Cancer Ther.* 2006
- inhibition of Notch-1 in genistein-treated BxPC–3 cells over time in Figure 8A in *Mol Cancer Ther.* 2006
- down-regulation of MMP–9 expression in Notch-1 siRNA transfected BxPC–3 cells in Figure 17A (left) in the Dissertation and Figure 3B in *Cancer Res.* 2006a
- up-regulation by cDNA transfection and down regulation by Notch-1 siRNA transfection in BcPC–3 cells in Figure 4B in *Cancer Res.* 2006a
- down-regulation of MMP–9 in ICN-transfected BxPC–3 cells in Figure 15B in the Dissertation and Figure 5A in *Cancer Res.* 2006a
- inhibition of Notch-1, Hes-1, Cyclin D1, and Bcl-X_L protein expression after 72 hours of curcumin treatment in pancreatic cancer cells in Figure 3D in *Cancer* 2006
- down-regulation of Notch-1 expression by curcumin and Notch-1 siRNA in Notch-1 siRNA-transfected BxPC–3 cells in Figure 5A in *Cancer* 2006
- down-regulation of Notch-1 expression in Notch-1 siRNA-transfected BxPC–3 cells compared with control in Figure 5A in *Cancer Res.* 2006b
- inhibition of Hes-1, Cyclin D1 and Bcl-xL in genistein-treated BxPC–3 cells over time in Figure 20C in the Dissertation and Figure 3C in *Int J Cancer* 2006
- inhibition of Bcl-xL, Bcl-2, Cyclin D1, COX–2, Survivin and MMP–9 protein expression by Notch-1 siRNA in BxPC–3 cells in Figure 6A in *Int J Cancer* 2006
- inhibition of IKKα and pIκBα protein expression by Notch-1 siRNA in BxPC–3 cells in Figure 6B in *Int J Cancer* 2006

Respondent reused and relabeled a second set of β-actin bands to represent loading controls for the following experiments showing:
- Increasing inhibition of Notch-1 by 25 μmol/l genistein at 24, 48, and 72 hours in BxPC–3 cells in Figure 20A in the Dissertation, Figure 7B in *Mol Cancer Ther.* 2006, and Figure 3A in *Int J Cancer* 2006
- up-regulation of Notch-1 in Notch-1 cDNA transfected BxPC–3 cells, with or without 10 μmol/l curcumin, in Figure 6A in *Cancer* 2006

Respondent reused and relabeled a third set of β-actin bands to represent loading controls for the following experiments showing:
- The level of expression of seven known G_0-G_1 cell cycle regulatory factors in Figure 10 in the Dissertation and Figure 5 in *Mol Cancer Ther.* 2006
- overexpression of Notch-1 in Notch-1 cDNA transfected BxPC–3 cells in Figure 22A in the Dissertation and Figure 9A in *Mol Cancer Ther.* 2006
- inhibition of NF-κB target gene expression by Notch-1 siRNA in BxPC–3 cells in Figure 23A in the Dissertation
- inhibition of IKKα and pIκBα protein expression by Notch-1 siRNA in BxPC–3 pancreatic cancer cells in Figure 23B the Dissertation
- overexpression of Notch-1 in Notch-1 siRNA–transfected BxPC–3 cells in Figure 1C in *Cancer Res.* 2006a
- down-regulation of VEGF by siRNA transfection in ICN-transfected BxPC–3 cells in Figure 5A (right) in *Cancer Res.* 2006a
- up-regulation of Notch-1 in cDNA-transfected and cDNA and ERRP transfected BxPC–3 cells in Figure 5C in *Cancer Res.* 2006b
- inhibition of MMP-2, MMP-9, and uPAR genes by FoxM1 siRNA in BxPC–3, HPAC, and PANC–1 cells in Figure 5B in *Cancer Res.* 2007b

Respondent reused and relabeled a fourth set of β-actin bands to represent loading controls for the following experiments showing:
- FoxM1 expression in AsPC–1, BxPC–3, Colo-357, HPAC, L3.6pl, MIA PaCa and PANC–1 cells in Figure 1A in *Cancer Res.* 2007b
- PDGF–D expression in PDGF–D cDNA transfected BxPC–3, Colo-357, and MIA PaCa cells in Figure 2C in *Cancer Res.* 2007c
- Bcl-2 expression in AsPC–1, BxPC–3, Colo-357, HPAC, L3.6pl, MIA PaCa and PANC–1 cells in Figure 1C in *Int J Cancer* 2008

Respondent reused and relabeled a fifth set of β-actin bands to represent loading controls for the following experiments showing:
- Down regulation of PDFG–D expression by PDGF–D siRNA in BcPC–3, HPAC, and Colo-357 cells and up-regulation of PDGF–D expression by PDGF–D cDNA in BxPC–3, Colo-357, and MIA PaCa cells in Figure 2C in *Cancer Res.* 2007c
- inhibition of Notch-1 expression by PDGF–D siRNA in BxPC–3, HPAC, and Colo-357 cells in Figure 4A in *Cancer Res.* 2007c

Respondent reused and relabeled a sixth set of β-actin bands to represent loading controls for the following experiments showing:
- Up-regulation of Notch-1 expression by cDNA in BxPC–3, HPAC, and PANC–1 cells in Figure 6D (bottom) in the Dissertation and Figure 1D in *Mol Cancer Ther.* 2006
- down-regulation of Notch-1 expression by Notch-1 siRNA and genistein in BxPC–3 cells in Figure 21 in the Dissertation and Figure 4A in *Int J Cancer* 2006

Respondent reused and relabeled a seventh set of β-actin bands to represent loading controls for the following experiments showing:
- Down-regulation of Notch-1 expression by Notch-1 siRNA in BxPC–3, HPAC, and PANC–1 cells in Figure 6D (top) in the Dissertation and Figure 1D in *Mol Cancer Ther.* 2006
- expression of Notch-1, Hes-1, and Cyclin D1 after incubation with recombinant ERRP in BxPC–3, HPAC, and PANC–1 cells in Figure 2C in *Cancer Res.* 2006b
- effects of ERRP, Erbitux, or Herceptin followed by exposure to TGF-α or HB–EGF on Notch-1 expression in BxPC–3 cells in Figure 2D in *Cancer Res.* 2006b
- down-regulation of FoxM1 expression by FoxM1 siRNA in BxPC–3, HPAC, and PANC–1 cells in Figure 1D in *Cancer Res.* 2007b
- the level of expression of seven known G_0-G_1 cell cycle regulatory factors (Survivin, cdc25A, p27, p21, Cyclin D1, Cyclin B, and CDK2) in Figure 4C in *Cancer Res.* 2007b

Respondent reused and relabeled:
- Invasion assay results showing a high level of penetration of Notch-1 cDNA-transfected cells through a Matrigel matrix in Figure 1D in *Cancer Res.* 2006a, to also represent control siRNA-transfected cells (controls) not transfected with MMP–9 or VEGF siRNA in Figure 5B in *Cancer Res.* 2006a
- sections from one image of an invasion assay to show a lower level of penetration of C4–2B cells through a Matrigel matrix after treatment with 10 μmol/L of B–DIM than in the control condition (DMSO) in Figure 6B in *Cancer Res.* 2007a

- sections from one image to show the penetration of both control and ERRP-treated HPAC cells through a Matrigel matrix in Figure 4 in *Cancer Res.* 2006b
- one image to show the penetration of ERRP-treated PANC–1 cells through a Matrigel matrix in Figure 4 in *Cancer Res.* 2006b to also show the penetration of TW–37 treated Colo-357 cells in Figure 5b in *Int J Cancer* 2008
- images of assays of endothelial tube formation after HUVACs were trypsinized and seeded with control siRNA transfected BxPC–3 or HPAC cells in Figure 6c in *Cancer Res.* 2007b
- a single gel shift band showing the no treatment control condition (CS) in an EMSA assay using BxPC–3 cells showing down regulation of NF-κB DNA binding by Notch-1 siRNA in Figures 11A and 14A in the Dissertation to also show:

—The control conditions (CP) in assays showing activation of NF-κB binding activity by Notch-1 plasmid (cDNA) transfection in Figures 11A and 14A in the Dissertation

—inhibition of NF-κB DNA binding activity after treatment with 25 μM genistein for 48 hours in Figure 19B in the Dissertation

- a single gel shift band showing the effect of Notch-1 siRNA transfection of BxPC–3 cells, showing inhibition of NF-κB DNA binding activity in Figures 11A and 14A in the Dissertation to also show NF-κB binding activity in BxPC–3 cells after treatment with 25 μM genistein in Figure 22C in the Dissertation
- a single gel shift band showing the effect of Notch-1 cDNA transfection of BxPC–3 cells, showing activation of NF-κB DNA binding activity in Figures 11A and 14A in the Dissertation to also show NF-κB binding activity in BxPC–3 cells in the no treatment control condition in an experiment showing the effect of genistein on binding in Figure 22C in the Dissertation
- a single gel shift band showing the no treatment control condition in an EMSA assay using HPAC cells showing down regulation of NF-κB DNA binding by Notch-1 siRNA in Figure 11A in the Dissertation to also show the no treatment control condition in the activation of NF-κB DNA binding after transfection with Notch-1 cDNA
- a single gel shift band showing the effect of 0 μM genistein on NF-κB binding activity in BxPC3 cells in Figure 19A the Dissertation to also show the effect of:

—25 μM of genistein for 0 hours in HPAC cells in Figure 19B in the Dissertation

—Notch-1 cDNA on NF-κB binding activity in Figure 22C in the Dissertation

- a single gel shift band showing the effect of 10 μM genistein on NF-κB binding activity in BxPC3 cells in Figure 19A in the Dissertation to also show the effect of:

—25 μM genistein for 24 hours in HPAC cells in Figure 19B in the Dissertation

—Notch-1 cDNA plus 25 μM genistein on NF-κB binding activity in Figure 22C in the Dissertation

- a single gel shift band showing the effect of Bcl-2 siRNA transfection of Colo-357 cells showing down-regulation of NF-κB DNA binding activity to also show the same effect with 500 nM TW–37 on Colo-357 cells in Figure 3a in *Int J Cancer* 2008

Respondent reused and relabeled images representing the retinoblastoma control protein (Rb) levels from one EMSA in multiple figures. Respondent used the same loading controls assay blots, in different orders with some flipped horizontally, showing:

- Down-regulation of Notch-1 gene expression by Notch-1 siRNA in siRNA- and cDNA-transfected BxPC–3, HPAC, and PANC–1 cells in Figure 11 in the Dissertation and Figure 6 in *Mol Cancer Ther.* 2006
- down-regulation of Notch-1 by genistein in BxPC–3 cells in Figure 7E in *Mol Cancer Ther.* 2006
- Notch-1 induced NF-κB DNA binding in Figure 14 in the Dissertation and Figure 2 in *Cancer Res.* 2006a
- down-regulation of Notch-1 by curcumin in BxPC–3 and PANC–1 cells in Figures 4, 5D, and 6D in *Cancer* 2006
- inhibition of NF-κB activation in three types of pancreatic cancer cells (BxPC–3, HPAC, PANC–1) in Figure 3A in *Cancer Res.* 2006b
- inhibition of NF-κB DNA binding activity by genistein (by dose and time) in Figure 19 in the Dissertation and Figure 2 in *Int J Cancer* 2006
- inhibition of NF-κB DNA-binding activity by Notch-1 siRNA in BxPC–3 pancreatic cancer cells in Figure 22 in the Dissertation and Figure 5 in *Int J Cancer* 2006
- decreased NF-κB DNA-binding activity through down-regulation of PDGF–D by siRNA transfection in BxPC–3, HPAC, and Colo-357 pancreatic cancer cells, activation of NF-κB DNA binding activity in BxPC3, Colo-357, and MIA PaCa pancreatic cancer cells in Figure 5A in *Cancer Research* 2007c
- differences in NF-κB activation in a panel of pancreatic cancer cell lines (AsPC–1, BxPC–3, Colo-357, HPAC, L3.6pl, MIA PaCa, PANC–1 in Figure 1d in *Int J Cancer* 2008
- inhibition of NF-κB activation by Bcl-2 siRNA in Colo-357 cells and by TW–37 (by dose and time) in Colo-357 and BXPC–3 pancreatic cancer cells in Figure 3a in *Int J Cancer* 2008
- inhibition of NF-κB activation by TW–37 in Colo-357 tumor xenografts from SCID mice in Figure 6c in *Int J Cancer* 2008

In addition, Respondent used these same images to represent β-actin in a figure showing that FoxM1 protein levels were up-regulated by FoxM1 cDNA plasmid in AsPC–1, PANC–1, and Colo-357 cells in Figure 1D in *Cancer Res.* 2007b.

Respondent reused and relabeled one image to represent multiple supershift assays done at different times for different experiments to show the effect of anti-NF-κB p65 antibody on NF-κB DNA-binding activity in:

- Figure 2B in *Cancer Res* 2006a
- Figure 5A in *Cancer Res.* 2007c

Respondent reused and relabeled a second image to represent multiple supershift assays done at different times for different experiments to show the effect of anti-NF-κB p65 antibody on NF-κB DNA-binding activity in:

- Figure 6D in *Mol Cancer Ther.* 2006
- Figure 4C in *Cancer* 2006
- Figure 3A in *Cancer Res.* 2006b
- Figure 2C in *Int J Cancer* 2006
- Figure 1d in *Int J Cancer* 2008

Respondent reused and relabeled the Rb levels in multiple supershift assay figures representing different experiments done at different times. Respondent used the same loading control assay blots in the supershift assays that came from the EMSAs to show the effect of anti-NF-κB p65 antibody on NF-κB DNA-binding activity in:

- Figure 6D in *Mol Cancer Ther.* 2006
- Figure 2B in *Cancer Res.* 2006a
- Figure 4C in *Cancer* 2006
- Figure 3A (right) in *Cancer Res.* 2006b
- Figure 2C in *Int J Cancer* 2006
- Figure 5A (right) in *Cancer Res* 2007c
- Figure 1d (right) in *Int J Cancer* 2008

The institution revoked the Respondent's Ph.D. degree and procured retractions or errata for all of the affected papers except *Mol Cancer Ther.* 2008.

Dr. Wang entered into a Voluntary Exclusion Agreement (Agreement) and agreed to the following:

(1) Respondent agreed to exclude himself voluntarily for a period of ten (10) years beginning on July 21, 2020, from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' pursuant to HHS's Implementation (2 CFR part 376) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180 (collectively the ''Debarment Regulations'');

(2) Respondent agreed to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of ten (10) years, beginning on July 21, 2020; and

(3) as a condition of the Agreement, Respondent will request that the following paper be corrected or retracted in accordance with 42 CFR 93.407(a)(1):

- *Mol. Cancer Ther.* 2008 Feb;7(2):341–9

Dated: August 7, 2020.

Elisabeth A. Handley,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2020–17602 Filed 8–11–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; AD Analysis.

Date: September 4, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 496–9667, *nijaguna.prasad@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 6, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–17586 Filed 8–11–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: September 10–11, 2020.

Closed: September 10, 2020, 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Fogarty International Center, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: September 11, 2020, 12:00 p.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned FIC activities.

Place: Fogarty International Center, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Meeting Access: https://www.fic.nih.gov/About/Advisory/Pages/default.aspx.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892–7952, (301) 496–1415, *kristen.weymouth@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx* where an agenda and additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: August 6, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–17589 Filed 8–11–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee Grant Review.

Date: September 11, 2020.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3185, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research

Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3185, Bethesda, MD 20892–9306, 301–402–0838, *barbara.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 7, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–17647 Filed 8–11–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6210–N–01]

Notice of Regulatory Waiver Requests Granted for the First Quarter of Calendar Year 2020

AGENCY: Office of the General Counsel, Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (the HUD Reform Act) requires HUD to publish quarterly **Federal Register** notices of all regulatory waivers that HUD has approved. Each notice covers the quarterly period since the previous **Federal Register** notice. The purpose of this notice is to comply with the requirements of section 106 of the HUD Reform Act. This notice contains a list of regulatory waivers granted by HUD during the period beginning on January 1, 2020 and ending on March 31, 2020.

FOR FURTHER INFORMATION CONTACT: For general information about this notice, contact Aaron Santa Anna, Acting Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10276, Washington, DC 20410–0500, telephone 202–708–3055 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

For information concerning a particular waiver that was granted and for which public notice is provided in this document, contact the person whose name and address follow the description of the waiver granted in the accompanying list of waivers that have been granted in the first quarter of calendar year 2020.

SUPPLEMENTARY INFORMATION:

Section 106 of the HUD Reform Act added a new section 7(q) to the Department of Housing and Urban Development Act (42 U.S.C. 3535(q)), which provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary or equivalent rank, and the person to whom authority to waive is delegated must also have authority to issue the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that HUD has approved, by publishing a notice in the **Federal Register**. These notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;

b. Describe the nature of the provision waived and the designation of the provision;

c. Indicate the name and title of the person who granted the waiver request;

d. Describe briefly the grounds for approval of the request; and

e. State how additional information about a particular waiver may be obtained.

Section 106 of the HUD Reform Act also contains requirements applicable to waivers of HUD handbook provisions that are not relevant to the purpose of this notice.

This notice follows procedures provided in HUD's Statement of Policy on Waiver of Regulations and Directives issued on April 22, 1991 (56 FR 16337). In accordance with those procedures and with the requirements of section 106 of the HUD Reform Act, waivers of regulations are granted by the Assistant Secretary with jurisdiction over the regulations for which a waiver was requested. In those cases in which a General Deputy Assistant Secretary granted the waiver, the General Deputy Assistant Secretary was serving in the absence of the Assistant Secretary in accordance with the office's Order of Succession.

This notice covers waivers of regulations granted by HUD from January 1, 2020 through March 31, 2020. For ease of reference, the waivers granted by HUD are listed by HUD program office (for example, the Office of Community Planning and Development, the Office of Fair Housing and Equal Opportunity, the Office of Housing, and the Office of Public and Indian Housing, etc.). Within each program office grouping, the waivers are listed sequentially by the regulatory section of title 24 of the Code of Federal Regulations (CFR) that is being waived. For example, a waiver of a provision in 24 CFR part 58 would be listed before a waiver of a provision in 24 CFR part 570.

Where more than one regulatory provision is involved in the grant of a particular waiver request, the action is listed under the section number of the first regulatory requirement that appears in 24 CFR and that is being waived. For example, a waiver of both § 58.73 and § 58.74 would appear sequentially in the listing under § 58.73.

Waiver of regulations that involve the same initial regulatory citation are in time sequence beginning with the earliest-dated regulatory waiver.

Should HUD receive additional information about waivers granted during the period covered by this report (the first quarter of calendar year 2020) before the next report is published (the second quarter of calendar year 2020), HUD will include any additional waivers granted for the first quarter in the next report.

Accordingly, information about approved waiver requests pertaining to HUD regulations is provided in the Appendix that follows this notice.

The Principal Deputy General Counsel, Michael B. Williams, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Samuel Pearson-Moore, who is the Federal Register Liaison for HUD, for purposes of publication in the **Federal Register**.

Dated: August 7, 2020.

Samuel Pearson-Moore,

Federal Register Liaison for the Department of Housing and Urban Development.

Appendix

Listing of Waivers of Regulatory Requirements Granted by Offices of the Department of Housing and Urban Development January 1, 2020 Through March 31, 2020

Note to Reader: More information about the granting of these waivers, including a copy of the waiver request and approval, may be obtained by contacting the person whose name is listed as the contact person directly after each set of regulatory waivers granted.

The regulatory waivers granted appear in the following order:

I. Regulatory waivers granted by the Office of Community Planning and Development.

II. Regulatory waivers granted by the Office of Fair Housing and Equal Opportunity.

III. Regulatory waivers granted by the Office of Housing.

IV. Regulatory waivers granted by the Office of Public and Indian Housing.

Regulatory Waivers Granted by the Office of Community Planning and Development (CPD)

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulations:* 24 CFR 91.105(c)(2) and (k), 24 CFR 91.115(c)(2) and (i).

Project/Activity: Citizen participation in substantial amendments to Consolidated Plans/Action Plans.

Nature of Requirement: 24 CFR 91.105(c)(2) and (k) for local governments and 24 CFR 91.115(c)(2) and (i) for States require that citizens be provided not less than 30 days to comment on substantial amendments to a jurisdiction's Consolidated Plan/Action Plan.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: Given the need to expedite actions to respond to COVID–19, HUD waived 24 CFR 91.105(c)(2) and (k), 91.115(c)(2) and (i) to balance the need to respond quickly to the growing spread and effects of COVID–19 with the statutory requirement to provide reasonable notice and opportunity for citizens to comment on substantial amendments concerning the proposed uses of funds provided under CPD's formula programs.

Applicability: The 30-day public comment period requirement is waived for substantial amendments, provided that no less than 5 days are provided for public comments on each substantial amendment. The waiver is available through the end of each jurisdiction's 2020 program year. Any jurisdiction wishing to undertake further amendments to prior year plans following the 2020 program year can do so during the development of its FY 2021 Annual Action Plan.

Contact: James Höemann, Office of Block Grant Assistance, Entitlement Communities Division, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7282, Washington, DC 20410, telephone (202) 402–5716. *james.e.hoemann@hud.gov*.

• *Regulations:* 24 CFR 91.105(c)(2) and (k), 24 CFR 91.115(c)(2) and (i), 24 CFR 91.401.

Project/Activity: Citizen participation in substantial amendments to Consolidated Plans/Action Plans.

Nature of Requirement: Jurisdictions that receive funding under formula programs administered by CPD are required to follow their citizen participation plans, which identify how they are to give their citizens the opportunity to comment on substantial amendments to the Consolidated Plan/Action Plan. Those opportunities are primarily provided by public hearings and citizen meetings.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date: March 31, 2020.

Justification: HUD recognizes the efforts to contain COVID–19 require limiting public gatherings, such as public hearings used to gather citizens' comments and that there is a need to respond quickly to the growing spread and effects of COVID–19. Therefore, HUD waived 24 CFR 91.105(c)(2) and (k), 24 CFR 91.115(c)(2) and (i) to allow jurisdictions to determine what constitutes reasonable notice and opportunity to comment given their circumstances.

Applicability: This authority is in effect through the end of each jurisdiction's 2020 program year.

Contact: Amy Palilonis, Office of HIV/AIDS Housing, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7248, Washington, DC 20410, telephone (202) 402–5916, *Amy.L.Palilonis@hud.gov*.

• *Regulation:* 24 CFR 92.252(d)(1) Utility Allowance Requirements.

Project/Activity: The city of Berkeley, California, requested a waiver of 24 CFR 92.252(d)(1) to allow use of the utility allowance established by local public housing agency (PHA) for a HOME-assisted project—Grayson Street Apartments.

Nature of Requirement: The regulation at 24 CFR 92.252(d)(1) requires participating jurisdictions to establish maximum monthly allowances for utilities and services (excluding telephone) and update the allowances annually. However, participating jurisdictions are not permitted to use the utility allowance established by the local public housing authority for HOME-assisted rental projects for which HOME funds were committed on or after August 23, 2013.

Granted By: David C. Woll Jr., Principal Deputy Assistant Secretary for Community Planning and Development.

Date Granted: February 11, 2020.

Reason Waived: The HOME requirements for establishing a utility allowances conflict with Project Based Voucher program requirements. It is not possible to use two different utility allowances to set the rent for a single unit and it is administratively burdensome to require a project owner establish and implement different utility allowances for HOME-assisted units and non-HOME assisted units in a project.

Contact: Virginia Sardone, Director, Office of Affordable Housing Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7160, Washington, DC 20410, telephone (202) 708–2684.

• *Regulation:* 24 CFR 92.300(a)(3) Rental Housing Developed by Community Housing Development Organizations (CHDO).

Project/Activity: The Newton HOME Consortium in Massachusetts, requested that HUD waive 24 CFR 92.300(a)(3) to permit a CHDO to transfer ownership of three HOME-assisted rental projects to the Newton Housing Authority to ensure that the units will be maintained as affordable housing for at least for the affordability period.

Nature of Requirement: This provision requires that rental housing developed with CHDO set-aside funds must be owned by the CHDO for a period at least equal to the period of affordability in 24 CFR 92.252.

Granted By: David C. Woll Jr., Principal Deputy Assistant Secretary for Community Planning and Development.

Date Granted: January 31, 2020.

Reason Waived: The Newton HOME Consortium provided HOME funds to Citizens for Affordable Housing in Newton Development Organization (CAN–DO), a CHDO, to develop 13 HOME-assisted rental projects. Of those 13 projects, three remain within the HOME affordability period and are subject to the 2013 HOME final rule. CAN–DO no longer has sufficient staff or resources to manage its HOME portfolio. Without a waiver, the affordable housing may fall into disrepair or be lost to foreclosure and the consortium would be required to repay the HOME funds invested.

Contact: Virginia Sardone, Director, Office of Affordable Housing Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7160, Washington, DC 20410, telephone (202) 708–2684.

• *Regulations:* 24 CFR 574.310(b).

Project/Activity: Property Standards for Tenant-Based Rental Assistance (TBRA).

Nature of Requirement: This section of the HOPWA regulations provides that units occupied by recipients of HOPWA TBRA meet the Housing Quality Standards (HQS) established in this section. This waiver is required to

enable grantees and project sponsors to expeditiously meet the critical housing needs of the many eligible families that have been affected by COVID–19 while also minimizing the spread of the coronavirus.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date: March 31, 2020.

Justification: This waiver is required to enable grantees and project sponsors to expeditiously meet the critical housing needs of the many eligible families that have been affected by COVID–19 while also minimizing the spread of the coronavirus.

Applicability: This waiver is in effect 4/1/2021, for recipients and project sponsors that are able to meet the following criteria:

a. The recipient or project sponsor is able to visually inspect the unit using technology, such as video streaming, to ensure the unit meets HQS before any assistance is provided; and

b. The recipient or subrecipient has written policies to physically reinspect the unit after the health officials determine special measures to prevent the spread of COVID–19 are no longer necessary.

Contact: Amy Palilonis, Office of HIV/AIDS Housing, Office of Community Planning and Development, Department of Housing and Development, 451 Seventh Street SW, Room 7248, Washington, DC 20410, telephone (202) 402–5916. *Amy.L.palilonis@hud.gov*.

• *Regulations:* 24 CFR 574.310(b)(2)(iii).

Project/Activity: Space and Security.

Nature of Requirement: This section of the HOPWA regulations provide that each resident must be afforded adequate space and security for themselves and their belongings.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date: March 31, 2020.

Justification: This waiver is required to enable grantees and project sponsors operating housing facilities and shared housing arrangements the flexibility to use optional appropriate spaces for quarantine services of eligible households affected by COVID–19. Optional spaces may include the placement of families in a hotel/motel room where family members may be required to utilize the same space not allowing for adequate space and security for themselves and their belongings.

Applicability: This space and security requirement is waived for grantees addressing appropriate quarantine space for affected eligible households during the allotted quarantined time frame recommended by local health care professionals.

Contact: Amy Palilonis, Office of HIV/AIDS Housing, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7248, Washington, DC 20410, telephone (202) 402–5916. *Amy.L.Palilonis@hud.gov*.

• *Regulations:* 24 CFR 574.320(a)(2).

Project/Activity: Rent Standards.

Nature of Requirement: Grantees must establish rent standards for their tenant-based rental assistance programs based on FMR (Fair Market Rent) or the HUD approved community-wide exception rent for unit size. Generally, the TBRA payment may not exceed the difference between the rent standard and 30 percent of the family's adjusted income.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date: March 31, 2020.

Justification: This waiver of the FMR rent standard limit permits HOPWA grantees to establish rent standards, by unit size, that are reasonable, and based upon rents being charged for comparable unassisted units in the area, taking into account the location, size, type, quality, amenities, facilities, management and maintenance of each unit.

Applicability: Such rent standards may be used for up to 4/1/2021.

Contact: Amy Palilonis, Office of HIV/AIDS Housing, Office of Community and Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7248, Washington, DC 20410, telephone (202) 402–5916. *Amy.L.Palilonis@hud.gov*.

• *Regulations:* 24 CFR 574.530.

Project/Activity: Records.

Nature of Requirement: Each grantee must maintain records to document compliance with HOPWA requirements, which includes determining the eligibility of a family to receive HOPWA assistance.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date: March 31, 2020.

Justification: This waiver will permit HOPWA grantees and project sponsors to rely upon a family member's self-certification of income and credible information on their HIV status (such as knowledge of their HIV-related medical care) in lieu of source documentation to determine eligibility for HOPWA assistance of families and grantees affected by COVID–19.

Applicability: This waiver is in effect for recipients who require written certification of the household seeking assistance of their HIV status and income, and agree to obtain source documentation of HIV status and income eligibility within 3 months of public health officials determining no additional special measures are necessary to prevent the spread of COVID–19.

Contact: Amy Palilonis, Office of HIV/AIDS Housing, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7248, Washington, DC 20410, telephone (202) 402–5916. *Amy.L.palilonis@hud.gov*.

• *Regulations:* 24 CFR 576.106(d)(1).

Project/Activity: Rental assistance funded under the Emergency Solutions Grants (ESG) Program.

Nature of Requirement: Under 24 CFR 576.106(d)(1), rental assistance cannot be provided unless the total rent is equal to or less than the FMR established by HUD, as provided under 24 CFR part 888, and complies with HUD's standard of rent reasonableness, as established under 24 CFR 982.507.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To assist recipients and subrecipients in quickly locating additional units to house individuals and families experiencing homelessness, which is necessary to prevent the spread of COVID–19.

Applicability: The FMR restriction is waived for any individual or family receiving rapid re-housing or homelessness prevention assistance who executes a lease for a unit between March 31 and September 30, 2020 so long as the recipient or subrecipient ensures that the units meet the rent reasonableness standard.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 576.107(a)(2).

Project/Activity: Homeless Management Information System (HMIS) activities funded under the ESG Program.

Nature of Requirement: 24 CFR 576.107(a)(2) requires the ESG recipient be the HMIS Lead in order to use ESG funds to pay eligible costs of hosting and managing the HMIS.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To allow more recipients to use ESG funding to upgrade or enhance the HMIS as needed to incorporate ESG program data related to COVID–19.

Applicability: The allowance for ESG recipients that are not the CoC designated HMIS Lead to pay for costs at 24 CFR 576.107(a)(2) is waived until September 30, 2020 to the extent the costs are necessary to incorporate data on ESG program participants and ESG activities related to COVID–19.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 576.401(b).

Project/Activity: Homelessness prevention and rapid re-housing assistance funded under the ESG Program.

Nature of Requirement: 24 CFR 576.401(b) requires recipients or subrecipients providing homelessness prevention assistance to re-evaluate the program participant's eligibility, and the types and amounts of assistance the program participant needs not less than once every three months.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To help program participants remain stable during the economic uncertainty caused by COVID–19.

Applicability: The requirement to re-evaluate program participants receiving homelessness prevention assistance not less than once every 3 months is waived until March 31, 2022 so long as the recipient or subrecipient conducts the required re-evaluations not less than once every 6 months.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 576.401(e).

Project/Activity: Housing stability case management funded under the ESG Program.

Nature of Requirement: 24 CFR 576.401(e) requires case managers to meet with program participants not less than once per month to assist program participants in ensuring long-term housing stability.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To help program participants remain stably housed and prevent the spread of COVID–19.

Applicability: The requirement for program participants to meet with a case manager not less than once per month is waived from March 31, 2020 until May 31, 2020.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.3, definition of permanent housing, 24 CFR 578.51(l)(1).

Project/Activity: Permanent housing projects funded under the Continuum of Care (CoC) Program.

Nature of Requirement: 24 CFR 578.3, definition of permanent housing, and 24 CFR 578.51(l)(1) require program participants residing in permanent housing to be the tenant on a lease for a term of one year that is renewable and terminable for cause.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To allow recipients to quickly identify permanent housing for individuals and families experiencing homelessness, which is helpful in preventing the spread of COVID–19.

Applicability: The requirement to have an initial lease term of one-year for permanent housing is waived until September 30, 2020, so long as the initial lease term of all leases is more than one month.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.37(a)(1)(ii)(F).

Project/Activity: Permanent housing-rapid re-housing projects funded under the CoC Program.

Nature of Requirement: 24 CFR 578.37(a)(1)(ii)(F) requires program participant of permanent housing-rapid re-housing projects to meet with a case manager at least monthly to assist them in ensuring long-term housing stability. The project is exempt from this requirement if the Violence Against Women Act of 1994 (42 U.S.C. 13925 *et seq.)* or the Family Violence Prevention and Services Act (42 U.S.C. 10401 *et seq.)* prohibits the recipient from making its housing conditional on the participant's acceptance of services.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To alleviate capacity issues of recipients and subrecipients as staff members are home for a variety of reasons related to COVID–19 and to solve the fact that not all program participants have the capacity to meet via phone or internet.

Applicability: The requirement that projects require program participants to meet with case managers not less than once per month is waived for all permanent housing-rapid re-housing projects until May 31, 2020.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.49(b)(2).

Project/Activity: Housing leased with CoC Program leasing funds.

Nature of Requirement: The CoC Program regulation at 24 CFR 578.49(b)(2) prohibits a recipient from using grant funds for leasing to pay above FMR when leasing individual units, even if the rent is reasonable when compared to other similar, unassisted units.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To assist recipients in locating additional units to house individuals and families experiencing homelessness and reduce the spread and harm of COVID–19.

Applicability: The FMR restriction on leasing individual units with CoC Program leasing dollars is waived until September 30, 2020. The affected recipient or subrecipient must still ensure that rent paid for individual units that are leased with CoC Program leasing dollars meet the rent reasonableness standard in 24 CFR 578.49(b)(2).

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.53(e)(8)(ii)(B) and 24 CFR 578.53(d).

Project/Activity: Housing search and counseling services funded under the CoC Program.

Nature of Requirement: 24 CFR 578.53(d) limits eligible supportive service costs to those explicitly listed in 24 CFR 53(e), which is more limited than what is eligible under the McKinney-Vento Act. 24 CFR 578.53(e)(8) allows recipients and subrecipients to use funds to pay for housing search and counseling services to help program participants locate, obtain, and retain suitable housing. 24 CFR 578.53(e)(8)(ii)(B) makes eligible the costs of credit counseling, accessing a free personal credit report, and resolving personal credit issues. However, the payment of rental or utility arrears is not included as an eligible cost.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To remove barriers to obtaining housing quickly and help reduce the spread and harm of COVID–19.

Applicability: The allowance to pay for up to 6 months of a program participants rental and utility arrears is in place until September 30, 2020 as necessary to help program participants obtain housing.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.75(b)(1).

Project/Activity: Leasing or rental assistance projects funded under the CoC Program.

Nature of Requirement: 24 CFR 578.75(b)(1) requires that recipients or subrecipients physically inspect each unit to assure that it meets HQS before any assistance will be provided for that unit on behalf of a program participant.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To prevent the spread of COVID–19 by limiting the in-person requirements of recipients.

Applicability: The requirement to physically inspect units before providing rental assistance or leasing assistance is waived until September 30, 2020. Recipients and subrecipients must be able to meet the following criteria: (1) The recipient is able to visually inspect the unit using technology to ensure the unit meets HQS before any assistance is provided; and (2) the recipient or subrecipient has written policies to physically re-inspect each unit within 3 months after health officials determine special measures to prevent the spread of COVID–19 are no longer necessary.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.75(b)(2).

Project/Activity: Leasing and rental assistance projects funded under the CoC Program.

Nature of Requirement: 24 CFR 578.75(b)(2) requires that recipients or subrecipients inspect each unit which are supported with leasing or rental assistance funds at least once annually during the grant period to ensure the units continue to meet HQS.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To prevent the spread of COVID–19 by limiting the in-person requirements of recipients.

Applicability: The requirement to re-inspect units to ensure they meet HQS is waived until March 31, 2021.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

• *Regulations:* 24 CFR 578.103(a) and 24 CFR 578.103(a)(4)(i)(B).

Project/Activity: Permanent Supportive Housing projects funded under the CoC Program; Program records.

Nature of Requirement: The CoC Program interim rule at 24 CFR 578.103(a) requires recipients to maintain records providing evidence they met program requirements and 24 CFR 578.103(a)(4)(i)(B) establishes the requirements for documenting disability for individuals and families that meet the ''chronically homeless'' definition in 24 CFR 578.3. Acceptable evidence of disability includes intake-staff recorded observations of disability that, no later than 45 days from the application for assistance, is confirmed and accompanied by evidence in paragraphs 24 CFR 578.103(a)(4)(i)(B)(1), (2), (3), or (5). HUD is waiving the requirement to obtain additional evidence.

Granted By: John Gibbs, Acting Assistant Secretary for Community Planning and Development.

Date Granted: March 31, 2020.

Reason Waived: To allow recipients to house people with observed disabilities quickly while providing recipients' intake staff with additional time to confirm disability from healthcare workers inundated by COVID–19 responses.

Applicability: The requirement to obtain third-party documentation of a qualifying individual's disability is waived until September 30, 2020.

Contact: Brett Esders, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7262, Washington, DC 20410, telephone (202) 708–4300, *brett.d.esders@hud.gov.*

II. Regulatory Waivers Granted by the Office of Fair Housing and Equal Opportunity

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR Section 115.305.

Project/Activity: Fair Housing Assistance Program Agencies-Temporary Waiver for Special Enforcement Effort (SEE) fund 20% limitation.

Nature of Requirement: As part of their participation in the FHAP, state and local agencies litigate cause findings in administrative hearings or in court.

Granted By: Anna Maria Farias, Assistant Secretary for Fair Housing and Equal Opportunity.

Date Granted: February 27, 2020.

Reason Waived: Commencing and maintaining litigation actions has become increasingly costly and may strain the capabilities of FHAP agencies. For FY2020, FHEO is providing an Enforcement Fund under its existing SEE fund authority set forth at 24 CFR 115.305 for the purpose of providing financial assistance to FHAP agencies struggling with these costs.

Contact: Erik Steinecker, Enforcement Branch, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410, telephone (202) 402–5158.

III. Regulatory Waivers Granted by the Office of Housing—Federal Housing Administration (FHA)

For further information about the following regulatory waivers, please see

the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 5.801 (C) (2).

Project/Activity: Annual financial statement due date.

Nature of Requirement: For specified Multifamily and Residential Care Borrowers otherwise required to submit Annual Financial Statements on or before April 30, 2020, extend the due date of the Borrower Annual Financial Statements from 90-days to 120-days after end of the fiscal year.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: March 18, 2020.

Reason Waived: Due to COVID–19 National Health Emergency the Borrower Annual Financial Statements have been extended by 30-days.

Contact: John Hartung, Director, Policy, Risk Analysis & Lender Relations Division, Office of Residential Care Facilities, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 1222 Spruce Street, 3rd Floor, St. Louis, MO 63103, telephone (314) 418–5238.

Regulation: 24 CFR 203.604.

Project/Activity: Single Family mortgagees are required to meet with mortgagor(s) face-to-face prior to foreclosing on a property that is insured with an FHA mortgage; however, in light of the COVID–19 pandemic, meetings in person presented a general health risk to both mortgagee employees and contractors as well as borrowers and the general public.

Nature of Requirement: 24 CFR 203.604, Contact with the Mortgagor, requires a mortgagee to meet with mortgagor(s) face-to-face prior to foreclosing on a property. The primary purpose of the meeting is to ascertain that the mortgagor is not eligible for a loss mitigation retention option that will enable the mortgagor to avoid foreclosure.

Granted By: Brian Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: March 13, 2020.

Reason Waived: To reduce risk of exposure to COVID–19 for both employees and contractors of the mortgagee and mortgagors.

Contact: Elissa O. Saunders, Acting Director, Office of Single Family Asset Management, Office of Housing, Department of Housing and Urban Development, 451 Seventh St. SW, Room 9278, Washington, DC 20410, telephone (202) 402–2378.

• *Regulation:* 24 CFR Section 219.220(b).

Project/Activity: Methouse Apartments, Project Number 033–SH012, Pittsburg, PA. Owner has requested to defer the Flexible Subsidy payments in order to apply for set-aside Tenant Protection Vouchers (''TPVs'').

Nature of Requirement: The Section 202 direct loan totaling $1,284,000, with a 3 percent interest rate matured April 1, 2019 and has been paid in full. Due to the limited cash flow, the project has not been able to meet the short and long-term improvement needs of the aging building. The project was awarded a Flexible Subsidy Operating Assistance Loan in the amount of $1,301,400 in 1991 at 3 percent interest per annum. The Flexible Subsidy Loan Agreements contain a provision requiring payment of the principal and the interest, in full, if the Section 202 direct mortgage loan is refinanced or paid in full. The request to defer the Flexible Subsidy payments as part of the owner's proposal to apply for set-aside tenant protection vouchers (TPV5), per Notice 2019–01, for the at-risk unassisted tenants at Methouse Apartments. Upon approval for the set-aside TPVs, the project will be better positioned financially to apply for a Section 223(f) loan to fund the needed $1,600,000 of short and long-term capital needs and repay the Flexible Subsidy Loan.

Granted By: Brian Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: February 5, 2020.

Reason Waived: The owner requested and was granted a waiver of the requirement to defer repayment of the Flexible Subsidy Operating Assistance Loan. An award of PBV vouchers under the Section 223(f) loan program will ensure preservation of affordable housing for individuals and family tenants in these low-income households.

Contact: John Ardovini, Branch Chief, Office of Recapitalization, Multifamily, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410, telephone (202) 402–3001.

• *Regulation:* 24 CFR 232.7.

Project/Activity: Golden Horizons of Crosslake FHA #092–22164, is an Assisted Living/Memory Care facility. The facility does not meet the requirements of 24 CFR 232.7 ''Bathroom'' of FHA's regulations. The project location is Crosslake, Minnesota.

Nature of Requirement: The regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom must be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: January 8, 2020.

Reason Waived: The project currently has a resident to shower ratio of 13:1. The memory care residents require assistance with bathing. These residents are housed in units in a secure, lock-down area, with a half-bathroom each and access to the shower rooms through a hallway. The project meets the State of Minnesota licensing requirements for bathing and toileting facilities.

Contact: John Hartung, Director of Policy, Risk Analysis & Lender Relations, Office of Residential Care Facilities, Office of Healthcare Programs, Department of Housing and Urban Development, 1222 Spruce Street, 3rd Floor, St. Louis, MO 63103, telephone (314) 418–5238.

• *Regulation:* 24 CFR 242.72.

Project/Activity: Metro Pavia Hospital Group, LLC (MPHG), headquartered in Guaynabo, Puerto Rico.

Nature of Requirement: 24 CFR 242.72 prohibits the leasing of hospitals by proposed Borrowers, effectively requiring that the owner (Borrower) of the facility and the operator of the facility be the same organization.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: March 24, 2020.

Reason Waived: The waiver will allow the Federal Housing Administration to refinance debt of MPHG through the hospital mortgage insurance program.

Contact: Paul Giaudrone, Underwriting Director, Office of Hospital Facilities, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 409 3rd Street SW, Washington, DC 20024, telephone (202) 708–0599.

Regulation: 24CFR 266.200(b)(2).

Project/Activity: California Housing Finance Agency, Sacramento, California, The Department requires, in 24 CFR 266.200(b)(2), Substantial Rehabilitation, that substantial rehabilitation (S/R) is defined as any combination of the following work to an existing facility of a project that aggregates to at least 15 percent of the project's value after the rehabilitation and that results in material improvement of the project's economic life, livability, marketability, and profitability.

Nature of Requirement: The Waiver of 24 CFR 266.200(b)(2), Substantial Rehabilitation. The waiver would

permit California Housing Finance Agency (CalHFA) to use the revised definition published in the Revised MAP Guide on January 29, 2016, such that S/R is: Any scope of work that either (a) exceeds in aggregate cost a sum equal to the 'base per dwelling unit limit' times the applicable * High Cost Factor, or (b) replacement of two or more building systems. 'Replacement is when the cost of replacement work exceeds 50 percent of the cost of replacing the entire system.

* The High Cost Factors for 2019 were published through a Housing Notice—2019–08 on May 20, 2019, and the revised statutory limits were recently published in the **Federal Register** on January 1, 2018. The 2019 base dwelling unit amount to determine substantial rehabilitation for FHA insured loan programs has been increased from $15,000 (changed from $6,500 per unit in the 2016 MAP guide) to $15,933. This amount will change annually based upon the change in the annual Consumer Price Index (CPI), along with the statutory limits or other inflation cost index published by HUD or CalHFA can utilize the approved amounts for the applicable year for both the High Cost Factor and base dwelling unit.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: February 21, 2020.

Reason Waived: CalHFA was approved as a Risk Share lender since 1994. It has originated $724 Million on Risk Share loans for 120 affordable housing developments with 12,120 units, and with a portfolio delinquency rate of less than 1%. CalHFA requests a waiver of two existing risk sharing requirements to meet agency's massive affordable housing needs in a post 1414B environment. The Department is approving your request for thirty (30) insured under the 542(c) HFA Risk Sharing Program expiring on December 31, 2023.

Contact: Patricia M. Burke, Director, Office of Multifamily Production, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410–8000, telephone (202) 402–5693.

• *Regulation:* 24 CFR 266.200(c)(2).

Project/Activity: The Waiver of 24 CFR 266.200(c)(2), Existing Project ''Equity Take-out'', that the refinancing of HFA refinance loan is permissible if the preservation is the result, with certain conditions: (1) Occupancy at least 93 percent for previous 12 months; (2) underwrite to the lower of Section 8 or market rents; (3) no equity take-outs: Risk sharing loan cannot exceed sum of existing indebtedness, cost of repairs, and transaction costs; (4) no defaults in the last 12 months of HFA loans. The waiver of 24 CFR 266.200(c)(2) would permit equity take-outs for any existing property, including both CalHFA-financed developments and those outside of CalHFA's portfolio, to be refinanced by CalHFA, where CalHFA and HUD split the risk of loss 50/50.

Nature of Requirement: The Waiver of 24 CFR 266.200(c)(2), Existing Projects ''Equity Take-outs''. The waiver of 24 CFR 266.200(c)(2) would permit equity take-outs for any existing property, including both CalHFA-financed developments and those outside of CalHFA's portfolio, to be refinanced by CalHFA, where CalHFA and HUD split the risk of loss 50/50.

The regulatory waiver is subject to the following conditions:

1. The waiver is limited to thirty (30) projects and expires on December 31, 2023 (*i.e.,* HUD issuance of a firm approval letter by December 31, 2023).

2. Ca1HFA must elect to take 50 percent or more of the risk of loss on all transactions;

3. In accordance with 24 CFR 266.200(d), the mortgage may not exceed an amount supportable by the lower of the Section 8 or comparable unassisted rents;

4. Projects must comply with Davis-Bacon labor standards in accordance with 24 CFR 266.225;

5. Ca1HFA must comply with regulations stated in 24 CFR 266.210 for insured advances or insurance upon completion transactions;

6. Occupancy is no less than 93 percent for previous 12 months;

7. No defaults in the last 12 months of the FIFA loan to be refinanced;

8. A 20-year affordable housing deed restriction placed on title that conforms to the Section 542 (c) statutory definition;

9. A Property Capital Needs Assessment (PCNA) must be performed and funds escrowed for all necessary repairs, and reserves funded for future capital needs; and;

10. For projects subsidized by Section 8 Housing Assistance Payment (HAP) contracts:

a: Owner agrees to renew HAP contract(s) for 20-year term, (subject to appropriations and statutory authorization, etc.), and b: In accordance with regulations in 24 CFR 883.306(e), and Housing Notice 2012–14—Use of ''New Regulation'' Section 8 Housing Assistance Payments (HAP) Contracts Residual Receipts of Offset Project-Based Section 8 Housing Assistance Payments, if at any time Ca1HFA determines that a project's excess funds (surplus cash) after project operations, reserve requirements and permitted distributions are met, CalHFA must place the excess funds into a separate interest-bearing account. Upon renewal of a HAP Contract the excess funds can be used to reduce future HAP payments or other project operations/purposes. When the HAP Contract expires, is terminated, or any extensions are terminated, any unused funds remaining in the Residual Receipt Account at the time of the contract's termination must be returned.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 21, 2020.

Reason Waived: HUD has reviewed and approved CalHFA's underwriting guidelines as indicted in Appendix B—Multifamily Loan Underwriting Standards and Reference Manual revised on November 2018. CalHFA will meet massive affordable housing needs in post CalHFA requests a waiver of two existing risk sharing requirements to meet agency's massive affordable housing needs in a post 1414B environment. The Department is approving your request for thirty (30) insured under the 542(c) HFA Risk Sharing Program expiring on December 31, 2023.

Contact: Patricia M. Burke, Director, Office of Multifamily Production, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 6132, Washington, DC, telephone (202) 402–5693.

• *Regulation:* 24 CFR 266.410(e).

Project/Activity: Rhode Island Housing, Providence, Rhode Island, no project name or number.

Nature of Requirement: The 24 CFR 266.410(e), which requires mortgages insured under the 542(c) Housing Finance Agency Risk Sharing Program to be fully amortized over the term of the mortgage. The waiver would permit Rhode Island Housing to use balloon loans that would have a minimum term of 17 years and a maximum amortization period of 40 years for the projects identified in the ''Multifamily Pipeline Projects''.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 3, 2020.

Reason Waived: The waiver was granted to allow Rhode Island Housing's clients additional financing options to their customers and to align Rhode Island Housing business practices with industry standards. Rhode Island Housing granted an amendment of the April 12, 2018 Waiver approval of 24

CFR 266.410(e) The regulatory waiver is subject to the following conditions:

1. The waiver is limited to twelve (12) transactions and expires on December 31, 2022.

2. Rhode Island Housing must elect to take 50 percent or more of the risk of loss on all transactions;

3. Mortgages made under this waiver may have amortization periods of up to 40 years, but with a minimum term of 17 years;

4. All other requirements of 24 CFR 266.410—Mortgage Provision remain applicable. The waiver is applicable only to loans made under Rhode Island Housing's Risk Sharing Agreement;

5. In accordance with 24 CFR 266.200(d), the mortgage may not exceed an amount supportable by the lower of the Section 8 or comparable unassisted rents;

6. Projects must comply with Davis-Bacon labor standards in accordance with 24 CFR 266.225;

7. Rhode Island Housing must comply with regulations stated in 24 CFR 266.210 for insured advances or insurance upon completion transactions;

8. The loans exceeding $50 million require a separate waiver request;

9. Occupancy is no less than 93 percent for previous 12 months;

10. No defaults in the last 12 months of the HFA loan to be refinanced;

11. A 20-year affordable housing deed restriction placed on title that conforms to the Section 542(c) statutory definition;

12. A Property Capital Needs Assessment (PCNA) must be performed and funds escrowed for all necessary repairs, and reserves funded for future capital needs; and

13. For projects subsidized by Section 8 Housing Assistance Payment (HAP) contracts:

i. a: Owner agrees to renew HAP contract(s) for 20-year term, (subject to appropriations and statutory authorization, etc.), and b: In accordance with regulations in 24 CFR 883.306(e), and Housing Notice 2012–14—Use of ''New Regulation'' Section 8 Housing Assistance Payments (HAP) Contracts Residual Receipts of Offset Project-Based Section 8 Housing Assistance Payments, if at any time Rhode Island Housing determines that a project's excess funds (surplus cash) after project operations, reserve requirements and permitted distributions are met, Rhode Island Housing must place the excess funds into a separate interest-bearing account. Upon renewal of a HAP Contract the excess funds can be used to reduce future HAP payments or other project operations/purposes. When the HAP Contract expires, is terminated, or any extensions are terminated, any unused funds remaining in the Residual Receipt Account at the time of the contract's termination must be returned.

Contact: Patricia M. Burke, Director, Office of Multifamily Production, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 6132, Washington, DC 20410, telephone (202) 402–5693.

• *Regulation:* 24 CFR 266.410(e).

Project/Activity: District of Columbia Housing Agency (DCHFA), Washington, DC, no project name or number.

Nature of Requirement: The 24 CFR 266.410(e), which requires mortgages insured under the 542(c) Housing Finance Agency Risk Sharing Program to be fully amortized over the term of the mortgage. The waiver would permit DCHFA to use balloon loans that would have a minimum term of 17 years and a maximum amortization period of 40 years for the projects identified in the ''Multifamily Pipeline Projects''.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 3, 2020.

Reason Waived: The waiver was granted to allow DCHFA's clients additional financing options to their customers and to align DCHFA business practices with industry standards, thus furthering the creation of a preservation of affordable housing throughout Washington, DC. The regulatory waiver is subject to the following conditions:

1. This waiver is limited to the projects listed in DCHFA's ''Multifamily Pipeline Projects'' and expires on December 31, 2022.

2. DCHFA must elect to take 50 percent or more of the risk of loss on all transactions.

3. Mortgages made under this waiver may have amortization periods of up to 40 years, but with a minimum term of 17 years.

4. All other requirements of 24 CFR 266.410—Mortgage Provision remain applicable. The waiver is applicable only to loans made under DCHFA's Risk Sharing Agreement.

5. In accordance with 24 CFR 266.200(d), the mortgage may not exceed an amount supportable by the lower of the Section 8 or comparable unassisted rents.

6. Projects must comply with Davis-Bacon labor standards in accordance with 24 CFR 266.225.

7. DCHFA must comply with regulations stated in 24 CFR 266.210 for insured advances or insurance upon completion transactions.

8. The loans exceeding $50 million require a separate waiver request.

9. Occupancy is no less than 93 percent for previous 12 months.

10. No defaults in the last 12 months of the HFA loan to be refinanced.

11. A 20-year affordable housing deed restriction placed on title that conforms to the Section 542(c) statutory definition.

12. A Property Capital Needs Assessment (PCNA) must be performed and funds escrowed for all necessary repairs, and reserves funded for future capital needs; and

13. For projects subsidized by Section 8 Housing Assistance Payment (HAP) contracts:

i. a: Owner agrees to renew HAP contract(s) for 20-year term, (subject to appropriations and statutory authorization, etc.), and b: In accordance with regulations in 24 CFR 883.306(e), and Housing Notice 2012–14—Use of ''New Regulation'' Section 8 Housing Assistance Payments (HAP) Contracts Residual Receipts of Offset Project-Based Section 8 Housing Assistance Payments, if at any time DCHFA determines that a project's excess funds (surplus cash) after project operations, reserve requirements and permitted distributions are met, DCHFA must place the excess funds into a separate interest-bearing account. Upon renewal of a HAP Contract the excess funds can be used to reduce future HAP payments or other project operations/purposes. When the HAP Contract expires, is terminated, or any extensions are terminated, any unused funds remaining in the Residual Receipt Account at the time of the contract's termination must be returned.

Contact: Patricia M. Burke, Director, Office of Multifamily Production, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 6132, Washington, DC 20410–8000, telephone (202) 402–5693.

• *Regulation:* 24 CFR 266.410(e).

Project/Activity: New York Housing Development Corporation (NYHDC), New York, New York, no project name or number.

Nature of Requirement: The 24 CFR 266.410(e), which requires mortgages insured under the 542(c) Housing Finance Agency Risk Sharing Program to be fully amortized over the term of the mortgage. The waiver would permit NYHDC to use balloon loans that would have a minimum term of 17 years and a maximum amortization period of 40 years for the projects identified in the ''Multifamily Pipeline Projects''.

Granted By: Brian D. Montgomery, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 3, 2020.

Reason Waived: The waiver was granted to allow NYHDC 's clients additional financing options to their customers and to align NYHDC business practices with industry standards, thus furthering the creation of a preservation of affordable housing throughout Washington, DC.

The regulatory waiver is subject to the following conditions:

1. The waiver is limited to ten (10) transactions and expires on December 31, 2021.

2. New York City Housing Development Corporation must elect to take 50 percent or more of the risk of loss on all transactions;

3. Mortgages made under this waiver may have amortization periods of up to 40 years, but with a minimum term of 17 years;

4. All other requirements of 24 CFR 266.410—Mortgage Provision remain applicable. The waiver is applicable only to loans made under New York City Housing Development Corporation's Risk Sharing Agreement;

5. In accordance with 24 CFR 266.200(d), the mortgage may not exceed an amount supportable by the lower of the Section 8 or comparable unassisted rents;

6. Projects must comply with Davis-Bacon labor standards in accordance with 24 CFR 266.225;

7. New York City Housing Development Corporation must comply with regulations stated in 24 CFR 266.210 for insured advances or insurance upon completion transactions;

8. The loans exceeding $50 million require a separate waiver request;

9. Occupancy is no less than 93 percent for previous 12 months of the HFA loan to be refinanced;

10. No defaults in the last 12 months of the HFA loan to be refinanced;

11. A 20-year affordable housing deed restriction placed on title that conforms to the Section 542(c) statutory definition.

12. A Property Capital Needs Assessment (PCNA) must be performed and funds escrowed for all necessary repairs, and reserves funded for future capital needs; and

13. For projects subsidized by Section 8 Housing Assistance Payment (HAP) contracts:

i. a: Owner agrees to renew HAP contract(s) for 20-year term, (subject to appropriations and statutory authorization, etc.), and b: In accordance with regulations in 24 CFR 883.306(e), and Housing Notice 2012–14—Use of ''New Regulation'' Section 8 Housing Assistance Payments (HAP) Contracts Residual Receipts of Offset Project-Based Section 8 Housing Assistance Payments, if at any time New York City Housing Development Corporation determines that a project's excess funds (surplus cash) after project operations, reserve requirements and permitted distributions are met, New York City Housing Development Corporation must place the excess funds into a separate interest-bearing account. Upon renewal of a HAP Contract the excess funds can be used to reduce future HAP payments or other project operations/purposes. When the HAP Contract expires, is terminated, or any extensions are terminated, any unused funds remaining in the Residual Receipt Account at the time of the contract's termination must be returned.

Contact: Patricia M. Burke, Director, Office of Multifamily Production, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 6132, Washington, DC 20410–8000, telephone (202) 402–5693.

II. Regulatory Waivers Granted by the Office of Public and Indian Housing

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 972.212(b).

Project/Activity: Housing Authority of St. Louis County (HASLC) Voluntary Conversion Application from Section 9 (public housing) to Section 8 (tenant voucher-based assistance) and a Voluntary Conversion Plan, identified as application DDAOO 10432.

Nature of Requirement: 24 CFR 972.212(b) states that HUD will not approve a voluntary conversion plan until completion of the required environmental review under part 58 or part 50.

Granted By: R. Hunter Kurtz, Assistant Secretary for Public and Indian Housing, granted this pursuant to 24 CFR 5.110, and found good cause to approve HASLC's request for the waiver noted above, thus allowing for PIH's approval of the subject Voluntary Conversion Plan and expediting the provision of tenant-based (Housing Choice Voucher) assistance for residents of the former Wellston Housing Authority public housing properties. Note that PIH did not waive the requirement in 24 CFR 972.212(b) that a Public Housing Authority (PHA) may not demolish or dispose of units or property until competition of the environmental review.

Date Granted: January 13, 2020.

Reason Waived: This will allow HASLC to request and receive Tenant Protection Vouchers (TPVs) from HUD and begin the process of converting the units from public housing by providing relocation opportunities to the residents with Housing Choice Voucher (HCV) tenant-based assistance.

Contact: Robert E. Mulderig, Deputy Assistant Secretary, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4130, Washington, DC 20410, telephone (202) 402–4780.

• *Regulation:* 24 CFR 972.218(a)–(e).

Project/Activity: Housing Authority of St. Louis County (HASLC) Voluntary Conversion Application from Section 9 (public housing) to Section 8 (tenant voucher-based assistance) and a Voluntary Conversion Plan, identified as application DDAOO 10432.

Nature of Requirement: 24 CFR 972.218(a)–(e) requires that a PHA submit a Conversion Assessment ''cost test.''

Granted By: R. Hunter Kurtz, Assistant Secretary for Public and Indian Housing, granted this pursuant to 24 CFR 5.110 and Section 22(b)(3) of the 1937 Act, and found good cause to approve HASLC's request for the waiver noted above, thus allowing for PIH's approval of the subject Voluntary Conversion Plan and expediting the provision of tenant-based (Housing Choice Voucher) assistance for residents of the former Wellston Housing Authority public housing properties.

Date Granted: January 13, 2020.

Reason Waived: This will allow HASLC to request and receive Tenant Protection Vouchers (TPVs) from HUD and begin the process of converting the units from public housing by providing relocation opportunities to the residents with Housing Choice Voucher (HCV) tenant-based assistance.

Contact: Robert E. Mulderig, Deputy Assistant Secretary, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4130, Washington, DC 20410, telephone (202) 402–4780.

• *Regulation:* 24 CFR 972.227(c)(1)(i).

Project/Activity: Housing Authority of St. Louis County (HASLC) Voluntary Conversion Application from Section 9 (public housing) to Section 8 (tenant voucher-based assistance) and a Voluntary Conversion Plan, identified as application DDAOO 10432.

Nature of Requirement: 24 CFR 972.227(c)(1)(i) requires for resident consultation specifically to include an explanation of the requirements of Section 22 of the 1937 Act as they apply to residents of the properties subject to Voluntary Conversion.

Granted By: R. Hunter Kurtz, Assistant Secretary for Public and Indian Housing, granted this pursuant to 24 CFR 5.110, and found good cause to approve HASLC's request for the waiver noted above, thus allowing for PIH's approval of the subject Voluntary Conversion Plan and expediting the provision of tenant-based (Housing Choice Voucher) assistance for residents of the former Wellston Housing Authority public housing properties.

Date Granted: January 13, 2020.

Reason Waived: This will allow HASLC to request and receive Tenant Protection Vouchers (TPVs) from HUD and begin the process of converting the units from public housing by providing relocation opportunities to the residents with Housing Choice Voucher (HCV) tenant-based assistance.

Contact: Robert E. Mulderig, Deputy Assistant Secretary, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4130, Washington, DC 20410, telephone (202) 402–4780.

[FR Doc. 2020–17658 Filed 8–11–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2020–N105; FXES11140100000–201–FF01E00000]

Proposed Habitat Conservation Plan for the Taylor's Checkerspot Butterfly and Three Subspecies of the Mazama Pocket Gopher, Puget Sound Energy; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), received an application from Puget Sound Energy (applicant) for an incidental take permit (ITP) pursuant to the Endangered Species Act of 1973, as amended. The ITP would authorize the applicant's take of three threatened subspecies of the Mazama pocket gopher incidental to otherwise lawful activities during replacement, repair, and upgrade of existing utility systems in Thurston County, Washington. The application includes a habitat conservation plan (HCP) with measures to minimize and mitigate the impacts of the taking on the covered species, including maintenance of occupied habitat. The HCP would also result in habitat improvement for the endangered Taylor's checkerspot butterfly, which is not a covered species, at one mitigation site. The Service has prepared a draft environmental action statement for our preliminary determination that the HCP and permit decision may be eligible for a categorical exclusion under the National Environmental Policy Act. We invite the public to review and comment on these documents.

DATES: To ensure consideration, please submit written comments by September 11, 2020.

ADDRESSES: To request further information or submit written comments, please use one of the following methods:

- *Internet:* You may view or download copies of the HCP, draft EAS, and additional information on the internet at *http://www.fws.gov/wafwo/.*
- *Email: wfwocomments@fws.gov.* Include ''PSE HCP'' in the subject line of the message.
- *U.S. Mail:* Public Comments Processing, Attn: FWS–R1–ES–2020–N105; U.S. Fish and Wildlife Service; Washington Fish and Wildlife Office; 510 Desmond Drive SE, Suite 102; Lacey, WA 98503.

FOR FURTHER INFORMATION CONTACT: Tim Romanski, Conservation Planning and Hydropower Branch Manager, Washington Fish and Wildlife Office, U.S. Fish and Wildlife Service (see **ADDRESSES**), telephone: 360–753–5823. If you use a telecommunications device for the deaf, please call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), received an application for an incidental take permit (ITP) pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). If the application is approved, the ITP would authorize the applicant's ''take'' of three threatened subspecies of the Mazama pocket gopher (*Thomomys mazama pugetensis, T. m. yelmensis,* and *T. m. tumuli*) incidental to otherwise lawful activities during replacement, repair, and upgrades of existing utility systems in Thurston County, Washington, for a period of 5 years. The application includes a habitat conservation plan (HCP) with measures to minimize and mitigate the impacts of the taking on the above covered species, and to improve habitat for the endangered Taylor's checkerspot butterfly (*Euphydryas editha taylori*), which is not a covered species. We have also prepared a draft environmental action statement (EAS) for our preliminary determination that the HCP and permit decision may be eligible for a categorical exclusion under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*).

Background

Puget Sound Energy proposes to conduct maintenance, replacement, and upgrades of existing electric power and natural gas systems in Thurston County, Washington. Covered activities may include pole replacement, cable or pipe repairs, and tree pruning projects for purposes of safety and efficiency. Work may also include conversion of overhead power lines to underground power lines in existing rights-of-way, short extension of existing feeder lines, and new gas service to existing homes where the gas supply pipes already exists at the street. In some cases, project activity would occur in potential habitat for three subspecies of the Mazama pocket gopher, but would not occur in critical habitat for these species. Puget Sound Energy would offset impacts to each of the covered species through the establishment and maintenance of permanent mitigation sites. Specifically, the applicant would permanently maintain suitable breeding, feeding and sheltering habitat for each of the covered species. In addition, the applicant would improve habitat for the Taylor's checkerspot butterfly at one mitigation site. However, the applicant does not anticipate any take of Taylor's checkerspot butterfly, and is not currently seeking ITP coverage for take of the Taylor's checkerspot butterfly.

The permit area includes 340,000 acres of lands in Thurston County, bounded to the west by the Black River and to the north by Interstate 5, and an area of more-preferred soils for the Mazama pocket gopher, as depicted in the HCP (Figure 3–1). The permit area encompasses lands where covered activities may occur, as well as 13 parcels of mitigation lands at 5 locations where mitigation would occur. The Service proposes to issue an ITP with a term limit of 5 years based on Puget Sound Energy's commitment to implement their proposed HCP, if permit issuance criteria are met.

Endangered Species Act

Section 9 of the ESA (16 U.S.C. 1531 *et seq.*) prohibits ''take'' of fish and wildlife species listed as endangered or threatened. Under the ESA, the term ''take'' means to harass, harm, pursue,

hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). The term ''harm,'' as defined in our regulations, includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). The term ''harass'' is defined in our regulations as to carry out intentional or negligent actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

Section 10(a)(1)(B) of the ESA contains provisions that authorize the Service to issue permits to non-Federal entities for the take of endangered and threatened species caused by otherwise lawful activities, provided the following criteria are met: (1) The taking will be incidental; (2) the applicant will, to the maximum extent practicable, minimize and mitigate the impact of such taking; (3) the applicant will ensure that adequate funding for the plan will be provided; (4) the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and (5) the applicant will carry out any other measures that the Service may require as being necessary or appropriate for the purposes of the plan. Regulations governing permits for endangered and threatened species are found in 50 CFR 17.22 and 17.32, respectively.

Public Comments

You may submit your comments and materials by one of the methods listed in **ADDRESSES**. We specifically request information, views, and suggestions from interested parties regarding our proposed Federal action, including adequacy of the HCP pursuant to the requirements for permits at 50 CFR parts 13 and 17 and adequacy of the EAS pursuant to the requirements of NEPA.

Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personally identifiable information in your comments, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

After public review, we will evaluate the permit application, associated documents, and any comments received to determine whether the permit application meets the requirements of section 10(a)(1)(B) of the ESA. We will also evaluate whether issuance of the requested section 10(a)(1)(B) permit would comply with section 7 of the ESA by conducting an intra-Service section 7 consultation under section 7(a)(2) of the ESA on the proposed ITP action. If we determine that the project qualifies for a categorical exclusion under NEPA because neither the permit nor the permit issuance is anticipated to significantly affect the quality of the human environment, we will finalize the EAS. The final NEPA and permit determinations will not be completed until after the end of the 30-day comment period, and will fully consider all comments received during the comment period. If we determine that all requirements are met, we will issue an ITP under section 10(A)(1)(B) of the ESA to the applicant for the take of the covered species, incidental to otherwise lawful covered activities.

Authority

We provide this notice in accordance with the requirements of section 10 of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA (42 U.S.C. 4321 *et seq.*), and their implementing regulations (50 CFR 17.32 and 40 CFR 1506.6, respectively).

Robyn Thorson,

Regional Director, U.S. Fish and Wildlife Service.

[FR Doc. 2020–17579 Filed 8–11–20; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–201–076 (Extension)]

Large Residential Washers: Extension of Action

AGENCY: United States International Trade Commission.

ACTION: Institution and Scheduling of an Investigation under section 204(c) of the Trade Act of 1974 (19 U.S.C. 2254(c)).

SUMMARY: Following receipt of a petition on August 3, 2020, requesting extension of the relief action currently in place on imports of large residential washers and parts thereof, the Commission on that date instituted investigation No. TA–201–076 (Extension) under section 204(c) of the Trade Act of 1974 (''the Act''). The purpose of this investigation is to determine whether the action taken by the President under section 203 of the Act with respect to large residential washers and covered parts, provided for in subheadings 8450.20.00, 8450.11.00, 8450.90.60, and 8450.90.20 of the Harmonized Tariff Schedule of the United States (HTS), continues to be necessary to prevent or remedy serious injury and whether there is evidence that the domestic industry is making a positive adjustment to import competition.

DATES: August 3, 2020.

FOR FURTHER INFORMATION CONTACT: Christopher W. Robinson (202–205–2542), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.— On January 23, 2018, the President, pursuant to section 203 of the Act (19 U.S.C. 2253), issued Proclamation 9694, imposing a safeguard measure on imports of certain large residential washers and parts thereof in the form of tariff-rate quotas. The proclamation was published in the **Federal Register** on January 25, 2018 (83 FR 3553). The measure took effect on February 7, 2018, for a period of three years and one day, or through February 7, 2021. The President imposed the measure following receipt of a report from the Commission in December 2017 under section 202 of the Trade Act (19 U.S.C. 2252) that contained an affirmative determination, remedy recommendations, and certain additional findings (see Large Residential Washers, Inv. No. TA–201–076, USITC Publication 4745, Dec. 2017).

Based on a petition filed on behalf of Whirlpool Corporation, Benton Harbor, Michigan, the Commission is instituting

this investigation, pursuant to section 204(c) of the Act. The purpose of this investigation is to determine whether the action taken by the President under section 203 of the Act with respect to large residential washers, provided for in subheading 8450.20.00 of the Harmonized Tariff Schedule of the United States (HTS), continues to be necessary to prevent or remedy serious injury and whether there is evidence that the domestic industry is making a positive adjustment to import competition. For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 206, subparts A and B (19 CFR part 206).

Participation in the investigation and public service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, not later than 21 days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance, and each party submitting a document for the consideration of the Commission in the course of this investigation must serve a copy of that document on all other parties in the manner provided by § 206.8 of the Commission's rules.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of confidential business information (CBI) under an administrative protective order (APO) and CBI service list.—Pursuant to § 206.54(e) of the Commission's rules, the Secretary will make CBI gathered in this investigation available to authorized applicants under the APO issued in the investigation in accordance with the procedures set forth in section 206.17 of the rules, provided that the application is made not later than 21 days after the publication of this notice in the **Federal Register**. The Secretary will maintain a separate service list for those parties authorized to receive CBI under the APO.

Hearing.—The Commission will hold a hearing in connection with this investigation beginning at 9:30 a.m. on November 5, 2020. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html* . Participating parties should check the Commission's website periodically for updates.

Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before October 27, 2020. All persons desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on October 29, 2020, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2) and 201.13(f) of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each participating party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is October 26, 2020. Parties may also file written testimony in connection with their presentation at the hearing and posthearing briefs. The deadline for filing posthearing briefs is November 12, 2020. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information on or before November 12, 2020. All written submissions must conform with the provisions of sections 201.8, 206.7, and 206.8 of the Commission's rules; any submissions that contain CBI must also conform with the requirements of sections 201.6 of the Commission's rules.

The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* further explains the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, will not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 206.8 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or CBI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of section 204(c) of the Act; this notice is published pursuant to § 206.3 of the Commission's rules.

By order of the Commission.

Issued: August 7, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–17615 Filed 8–11–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Non-Invasive Aesthetic Body-Contouring Devices, Components Thereof, and Methods of Using Same DN 3484;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of BTL Industries, Inc. on August 5, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain non-invasive aesthetic body-contouring devices, components thereof, and methods of using same. The complaint names as respondents: Allergan Limited of Ireland; Allergan USA, Inc. of Madison, NJ; Allergan, Inc. of Madison, NJ; Zeltiq Aesthetics, Inc. of Pleasanton, CA; Zeltiq Ireland Unlimited Company of Ireland; and Zimmer MedizinSysteme GmbH of Germany. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3484'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary *at EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 6, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–17618 Filed 8–11–20; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On August 6, 2020, the Department of Justice and the State of California on behalf of the California Department of Toxic Substances Control (''DTSC'') lodged a proposed Consent Decree with the United States District Court for the Central District of California pertaining to environmental contamination at the Dual Site Groundwater Operable Unit (''Dual Site OU'') of the Montrose Chemical Corp. and Del Amo Superfund Sites, in Los Angeles County, California. This proposed Consent Decree was lodged in the case *United States of America and State of California* vs. *Montrose Chemical Corp. of California et al.,* Civil Action No. 2:90–cv–03122 DOC (C.D. Cal.); it resolves certain of the claims in that case.

The proposed Consent Decree, titled in full ''Partial Consent Decree (Dual Site Operable Unit—Chlorobenzene Plume Remedy Operation and Maintenance)'', resolves certain claims or potential claims under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606, 9607, as well as certain

potential state law claims, in connection with environmental contamination at the Dual Site OU. The settling defendants are TFCF America, Inc.; Bayer CropScience Inc.; Montrose Chemical Corporation of California; Stauffer Management Company LLC; and JCI Jones Chemicals Inc. The Consent Decree requires the settling defendants to perform long-term operation and maintenance of the Chlorobenzene Plume Remedy at the Dual Site OU, and to make a payment of $4,000,000.00 toward the United States' unreimbursed Dual Site OU past costs and a payment of $177,265.36 towards DTSC's Dual Site OU past costs. (These same settling defendants, other than JCI Jones Chemicals Inc., have already committed in a previously approved partial consent decree to perform construction of the Chlorobenzene Plume Remedy.) The proposed Consent Decree also requires the settling defendants to pay the United States' and DTSC's future response costs for overseeing the work the settling defendants will be performing at the Dual Site OU.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and State of California* vs. *Montrose Chemical Corp. of California et al.,* D.J. Ref. Nos. 90–11–3–511 and 90–11–2–933/3. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.usdoj.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $96.00 (25 cents per page reproduction cost) for the Consent Decree, payable to the United States Treasury. For a paper copy without the appendices and signature pages, the cost is $22.25.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–17580 Filed 8–11–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Joseph J. Perillo, et al.,* Case No. 1:19–cv–07763, was lodged with the United States District Court for the Northern District of Illinois (Eastern Division) on August 5, 2020.

This proposed Consent Decree concerns a complaint filed by the United States against Defendants Joseph J. Perillo, Perillo Motor Cars, Inc., and Gold Coast Motor Cars, Inc. d/b/a Perillo Collision Center, pursuant to Sections 10 and 14 of the Rivers and Harbors Appropriation Act of 1899, 33 U.S.C. 403, 406, 408 and 413, and Sections 301(a) and 309(b) of the Clean Water Act, 33 U.S.C. 1311(a) and 1319(b), to obtain injunctive relief from and impose civil penalties against the Defendants for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations by requiring the Defendants to perform restoration and mitigation, and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Kurt N. Lindland, Assistant United States Attorney, United States Attorney's Office for the Northern District of Illinois, 219 South Dearborn Street, Chicago, IL 60604 and refer to *United States* v. *Joseph J. Perillo, et al.,* DJ # 90–5–1–1–21676.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Northern District of Illinois, Everett McKinley Dirksen United States Courthouse, 219 South Dearborn Street, Chicago, IL 60604. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/consent-decrees.*

Cherie Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2020–17591 Filed 8–11–20; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Information Collection; Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: National Science Foundation.

ACTION: Notice; request for comment.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of the date of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission may be obtained by calling 703–292–7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Title: Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

Abstract: A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership.

This proposed information collection activity provides a means to garner customer and stakeholder feedback in an efficient, timely manner in accordance with the Administration's commitment to improving customer service delivery as discussed in Section 280 of OMB Circular A–11 at *https://www.performance.gov/cx/a11-280.pdf.*

As discussed in OMB guidance, agencies should identify their highest-impact customer journeys (using customer volume, annual program cost, and/or knowledge of customer priority as weighting factors) and select touchpoints/transactions within those journeys to collect feedback.

These results will be used to improve the delivery of Federal services and programs. It will also provide government-wide data on customer experience that can be displayed on *www.performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

NSF will only submit collections if they meet the following criteria.

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used for general service improvement and program management purposes
- Upon agreement between OMB and the agency all or a subset of information may be released as part of A–11, Section 280 requirements only on *performance.gov.* Summaries of customer research and user testing activities may be included in public-facing customer journey maps or summaries.
- Additional release of data must be done coordinated with OMB.

These collections will allow for ongoing, collaborative and actionable communications between the Agency, its customers and stakeholders, and OMB as it monitors agency compliance on Section 280. These responses will inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on services will be unavailable.

Current Action: New Collection of Information.

Type of Review: New.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: Below is a preliminary estimate of the aggregate burden hours for this new collection. NSF will provide refined estimates of burden in subsequent notices.

Average Expected Annual Number of Activities: Approximately five types of customer experience activities such as feedback surveys, focus groups, user testing, and interviews.

Average Number of Respondents per Activity: 1 response per respondent per activity.

Annual Responses: 2,001,550.

Average Minutes per Response: 2 minutes–60 minutes, dependent upon activity.

Burden Hours: NSF requests approximately 101,125 burden hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a hFederal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Dated: August 6, 2020.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2020–17573 Filed 8–11–20; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0027]

Information Collection: International Atomic Energy Agency Design Information Questionnaire

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on our intention to request the Office of Management and Budget's (OMB) approval for renewal of an existing information collection in order for the United States to fulfill its responsibilities as a participant in the U.S./International Atomic Energy Agency (IAEA) Safeguards Agreement. The information collection is entitled, ''IAEA Design Information Questionnaire.''

DATES: Submit comments by September 11, 2020. Comments received after this date will be considered if it is practical to do so, but the Commission is able to

ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0027 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0027.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The final OMB Supporting Statement for the IAEA Design Information Questionnaire Forms is available in ADAMS under Accession No. ML20160A392. For the convenience of the reader, instructions about obtaining supplemental documents related to each information collection are provided in the ''Availability of Documents'' section.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Design Information Questionnaire—IAEA N–71 and Associated Forms N–72, N–73, N–74, N–75, N–76, N–77, N–91, N–92, N–93, N–94. ''. The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 20, 2020; 85 FR 16149.

1. *The title of the information collection:* IAEA Design Information Questionnaire Forms.
2. *OMB approval number:* 3150–0056.
3. *Type of submission:* Extension.
4. *The form number if applicable:* N/A.
5. *How often the collection is required or requested:* 1 time per year.
6. *Who will be required or asked to respond:* Licensees of facilities on the U.S. eligible list who have been notified in writing by the NRC to submit the form.
7. *The estimated number of annual responses:* 2.
8. *The estimated number of annual respondents:* 2.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 360 reporting hours.
10. *Abstract:* In order for the United States to fulfill its responsibilities as a participant in the U.S./International Atomic Energy Agency (IAEA) Safeguards Agreement, the NRC must collect information from licensees about their installations and provide it to the IAEA. Licensees of facilities that appear on the U.S. eligible list and have been notified in writing by the NRC are required to complete and submit a Design Information Questionnaire (DIQ), IAEA DIQ Form to provide information concerning their installation for use by the IAEA.

III. Availability of Documents

The supplemental documents related to each information collections are identified in the following table and are available to interested persons in ADAMS.

Old form title	New document title	ADAMS Accession No.
N–72	Research and Power Reactors DIQ Form	ML20217L473.
N–73	Conversion and/or Fuel Fabrication Plants DIQ Form	ML20217L470.
N–74	Reprocessing Plants DIQ Form	ML20217L472.
N–75	Isotopic Enrichment Plants DIQ Form	ML20217L471.
N–76	Geological Repositories DIQ Form	ML20217L467.
N–77	Spent Fuel Encapsulation Plants DIQ Form	ML20217L469.
N–92	Research and Development Facilities DIQ Form	ML20217L576.
N–93	Critical (Sub-Critical) Facilities DIQ Form	ML20217L466.
N–94	Separate Storage Installations DIQ Form	ML20217L468.

Dated: August 7, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–17622 Filed 8–11–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–333; NRC–2020–0025]

Exelon Generation Company, LLC; James A. FitzPatrick Nuclear Power Plant

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (the licensee) to withdraw its application dated September 5, 2019, as supplemented by letters dated November 6, 2019; February 21, 2020; and March 31, 2020, for a proposed amendment to Renewed Facility Operating License No. DPR–59 for the James A. FitzPatrick Nuclear Power Plant. The proposed amendment would have revised the allowable value for reactor water cleanup system primary containment isolation.

DATES: August 12, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0025 or NRC Docket No. 50–333 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0025. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

FOR FURTHER INFORMATION CONTACT: Justin C. Poole, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2048, email: *Justin.Poole@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted Exelon Generation Company, LLC's, request dated July 28, 2020 (ADAMS Accession No. ML20210M333), to withdraw its application dated September 5, 2019, as supplemented by letters dated November 6, 2019; February 21, 2020; and March 31, 2020 (ADAMS Accession Nos. ML19248B085, ML19310D579, ML20052E056, and ML20091F513, respectively), for a proposed amendment to Renewed Facility Operating License No. DPR–59 for the James A. FitzPatrick Nuclear Power Plant located in Oswego County, New York.

The proposed amendment would have revised the allowable value for reactor water cleanup system primary containment isolation. The proposed amendment was noticed in the **Federal Register** on January 28, 2020 (85 FR 5053).

Dated: August 6, 2020.

For the Nuclear Regulatory Commission.

Richard V. Guzman,

Senior Project Manager, Plant Licensing Branch I, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–17554 Filed 8–11–20; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval without change.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of the collection of information on qualitative feedback on PBGC's service delivery (OMB Control Number 1212–0066; expires October 31, 2020). This notice informs the public of PBGC's request and solicits comments on the information collection. This collection of information was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery.

DATES: Comments must be received on or before September 11, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the request will be posted on PBGC's website at *https://www.pbgc.gov/prac/laws-and-regulation/federal-register-notices-open-for-comment.* It may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–326–4040.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington DC 20005–4026; 202–229–6563. (TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–229–6563.)

SUPPLEMENTARY INFORMATION: The information collection activity will gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with PBGC's commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions, but the information requests are not statistical surveys that yield quantitative results generalizable to the population of interest. This feedback provides insights into customer or stakeholder perceptions, experiences and expectations, provides early warnings of issues with service, and focuses attention on areas where changes in PBGC's communication with the public, in training of staff, or in operations might improve the delivery of products or services. These collections will allow

for ongoing, collaborative and actionable communications between PBGC and its customers and stakeholders. These collections also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback targets areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information were not collected, vital feedback from customers and stakeholders on PBGC's services would be unavailable.

PBGC only submits a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of interest.

As noted, feedback collected under this generic clearance does not produce results generalizable to the population of interest. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Collections with such objectives require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

The collection of information has been approved by OMB under control number 1212–0066 (expires October 31, 2020). On May 27, 2020, PBGC published in the **Federal Register** (at 85 FR 31824) a notice informing the public of its intent to request an extension of this collection of information without modification. PBGC did not receive any comments about this collection of information. PBGC is requesting that OMB extend its approval for another three years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Annually, over the next three years, PBGC estimates that it will conduct three activities involving about 1,630 respondents, each of whom will provide one response. The number of respondents will vary by activity: 40 for usability testing, 90 for focus groups (nine groups of ten respondents), and 1,500 for customer satisfaction surveys. PBGC estimates the annual burden of this collection of information as 635 hours: 2 hours per response for usability testing (total 80 hours); 2 hours per response for focus groups (total 180 hours); and 15 minutes per response for customer satisfaction surveys (total 375 hours). No cost burden to the public is anticipated.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2020–17629 Filed 8–11–20; 8:45 am]

BILLING CODE 7709–02–P

OFFICE OF PERSONNEL MANAGEMENT

[3206–0235]

Submission for Review:, Letter Reply To Request for Information, RI 20–64; Former Spouse Survivor Annuity Election, RI 20–64A; Information on Electing a Survivor Annuity for Your Former Spouse, RI 20–64B

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request, (ICR), Letter Reply to Request for Information, RI 20–64; Former Spouse Survivor Annuity Election, RI 20–64A; and Information on Electing a Survivor Annuity for Your Former Spouse, RI 20–64B.

DATES: Comments are encouraged and will be accepted until September 11, 2020.

ADDRESS: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0235) was previously published in the **Federal Register** on March 23, 2020 at 85 FR 16394, allowing for a 60-day public comment period. No comments were received. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 20–64, Letter Reply to Request for Information, is used by the Civil Service Retirement System (CSRS) to provide information about the amount of annuity payable after a survivor reduction, to explain the annuity reductions required to pay for the survivor benefit, and to give the beginning rate of survivor annuity. RI 20–64A, Former Spouse Survivor Annuity Election, is used by the CSRS to obtain a survivor benefit election from annuitants who are eligible to elect to provide survivor benefits for a former spouse. RI 20–64B, Information on Electing a Survivor Annuity for Your Former Spouse, is a pamphlet that provides important information to retirees under the CSRS who want to provide a survivor annuity for a former spouse.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Letter Reply to Request for Information; Former Spouse Survivor Annuity Election.

OMB Number: 3206–0235.

Frequency: On occasion.

Affected Public: Individual or Households.

Number of Respondents: 38.

Estimated Time per Respondent: 45 minutes for RI 20–64A and 8 minutes for RI 20–64.

Total Burden Hours: 24 hours.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–17571 Filed 8–11–20; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

[3206–0187]

Submission for Review; We Need Information About Your Missing Payment, RI 38–31

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR), We Need Information about Your Missing Payment, RI 38–31.

DATES: Comments are encouraged and will be accepted until September 11, 2020.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent by email to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on March 27, 2020 at 85 FR 17370 allowing for a 60-day public comment period. No comments were received for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;

2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 38–31 is sent in response to a notification by an individual of the loss or non-receipt of a payment from the Civil Service Retirement and Disability Fund. Minor textual changes were made to request the information needed to enable OPM to trace and/or reissue payment. Missing payments may also be reported to OPM by a telephone call.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: We Need Information about Your Missing Payment.

OMB: 3206–0187.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 8,000.

Estimated Time per Respondent: 10 minutes.

Total Burden Hours: 1,333 hours.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–17569 Filed 8–11–20; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

[3206–0216]

Submission for Review: We Need Important Information About Your Eligibility for Social Security Disability Benefits, RI 98–7

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to

comment on a revised information collection request (ICR), We Need Important Information About Your Eligibility for Social Security Disability Benefits, RI 98–7.

DATES: Comments are encouraged and will be accepted until September 11, 2020.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent by email to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106) OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on March 23, 2020 at Volume 85 FR 16389 allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;
2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 98–7 is used by OPM to verify receipt of Social Security Administration (SSA) disability benefits, to lessen or avoid overpayment to Federal Employees Retirement System (FERS) disability retirees. It notifies the annuitant of the responsibility to notify OPM if SSA awards disability benefits and the subsequent overpayment that will occur with the receipt of both benefits.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: We Need Important Information about Your Eligibility for Social Security Disability Benefits.

OMB Number: 3206–0216.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 4,300.

Estimated Time per Respondent: 5 minutes.

Total Burden Hours: 358.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–17570 Filed 8–11–20; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89494; File No. SR–CBOE–2020–070]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Introduce a New Data Product To Be Known as Intraday Open-Close Data

August 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product to be known as Intraday Open-Close Data.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a new data product on Cboe to be known as Intraday Open-Close Data, which will be available for purchase to Cboe Trading Permit Holders (''TPHs'') and non-TPHs.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Intraday Open-Close Data available for purchase to TPHs and non-TPHs on the LiveVol DataShop website.[6]

Currently, the Exchange offers Open-Close Data, which is an end-of-day volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), price, and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange intends to submit a separate rule filing to establish fees for Open-Close Data.

[6] *See https://datashop.cboe.com/.*

transaction type (opening or closing). The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Open-Close Data is proprietary Cboe trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Now, the Exchange is proposing to offer an additional product, the Intraday Open-Close Data. The Intraday Open-Close Data will provide similar information to that of Open-Close Data, but will be produced and updated every 10 minutes during the trading day. Data is captured in ''snapshots'' taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10 minute period. For example, subscribers to the intraday product will receive the first calculation of intraday data by approximately 9:45 a.m. ET, which represents data captured from 9:30 a.m. to 9:40 a.m. Subscribers will receive the next update by 9:55 a.m., representing the data previously provided aggregated with data captured up to 9:50 a.m., and so forth. Each update will represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus will provide open-close data on an aggregate basis. The Intraday Open-Close Data will provide a volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), and transaction type (opening or closing). The customer and professional customer volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Intraday Open-Close Data is proprietary Cboe trade data and does not include trade data from any other exchange. In contrast to the existing Open-Close Data product, the Intraday Open-Close Data will not provide execution price.[7]

The Exchange will establish a monthly subscriber fee for Intraday Open-Close Data by way of a separate proposed rule change, which the Exchange will submit in connection with the launch of the Intraday Open-Close market data product.

The Exchange anticipates a wide variety of market participants to purchase Intraday Open-Close Data, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed Open-Close Data product may also provide helpful trading information regarding investor sentiment that may allow market participants to make better trading decisions throughout the day and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on Cboe. For example, intraday open data may allow a market participant to identify new interest or possible risks throughout the trading day, while intraday closing data may allow a market participant to identify fading interests in a security. The proposal is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that other exchanges offer a similar data product.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which may promote better informed trading throughout the trading day. Moreover, other exchanges offer a similar data product.[11]

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which as noted above, may promote better informed trading. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data on an intraday basis, and create and test trading models and analytical strategies. The Exchange believes Intraday Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

Moreover, other exchanges also off a substantially identical data product.[12] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline (''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. PHOTO and NOTO provide substantially the same information as that included in the proposed Intraday Open-Close Data product. Further, like the proposed product, the data is provided to subscribers cumulatively every 10 minutes and is available to

[7] Price information is not included in Intraday Open-Close Data because it cannot be provided within the time parameters necessary to generate the file.

[8] *See* Securities Exchange Act Release No. 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); *See also* Securities Exchange Act Release No. 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] *See* supra note 8.

[12] *Id.*

subscribers within five minutes of the conclusion of each 10 minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[13] The Exchange is proposing to introduce Intraday Open-Close Data in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least two other U.S. options exchanges offer a market data product that is similar to the Intraday Open-Close Data.[14] As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6)[16] thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay.[17] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Specifically, waiver of the operative delay will allow the Exchange to offer to investors without delay an optional historical data product that is substantially similar to products offered by other options exchanges. The proposal therefore does not present any novel issues and, accordingly, the Commission designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–CBOE–2020–070 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2020–070. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–070 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17558 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[13] *Id.*

[14] *Id.*

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89498; File No. SR–CboeEDGX–2020–036]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Introduce a New Data Product To Be Known As Intraday Open-Close Data

August 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or '' ''EDGX'' '') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product to be known as Intraday Open-Close Data. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a new data product on EDGX to be known as Intraday Open-Close Data, which will be available for purchase to EDGX Members (''Members'') and non-Members.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Intraday Open-Close Data available for purchase to Members and non-Members on the LiveVol DataShop website.[6] The Exchange also proposes to amend Exchange Rule 21.15(b) to provide that the Open-Close Data product will be available on an end-of-day basis and intraday basis.

Currently, the Exchange offers Open-Close Data, which is an end-of-day volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), price, and transaction type (opening or closing). The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Open-Close Data is proprietary EDGX trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Now, the Exchange is proposing to offer an additional product, the Intraday Open-Close Data. The Intraday Open-Close Data will provide similar information to that of Open-Close Data, but will be produced and updated every 10 minutes during the trading day. Data is captured in ''snapshots'' taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10 minute period. For example, subscribers to the intraday product will receive the first calculation of intraday data by approximately 9:45 a.m. ET, which represents data captured from 9:30 a.m. to 9:40 a.m. Subscribers will receive the next update by 9:55 a.m., representing the data previously provided aggregated with data captured through 9:50 a.m., and so forth. Each update will represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus will provide open-close data on an aggregate basis. The Intraday Open-Close Data will provide a volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), and transaction type (opening or closing). The customer and professional customer volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Intraday Open-Close Data is proprietary EDGX trade data and does not include trade data from any other exchange. In contrast to the existing Open-Close Data product, the Intraday Open-Close Data will not provide execution price.[7]

A description of each market data product offered by the Exchange is described in Exchange Rule 21.15(b). The Exchange proposes to amend Rule 21.15(b)(5) to provide that Open-Close Data will be offered on an end-of-day and intraday basis.

The Exchange will establish a monthly subscriber fee for Intraday Open-Close Data by way of a separate proposed rule change, which the Exchange will submit in connection with the launch of the Intraday Open-Close market data product.

The Exchange anticipates a wide variety of market participants to purchase Intraday Open-Close Data, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed Open-Close Data product may also provide helpful trading information regarding investor sentiment that may allow market participants to make better trading decisions throughout the day and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on EDGX. For example, intraday open data may allow a market participant to identify new interest or possible risk throughout the trading day, while intraday closing data may allow a market participant to identify fading interests in a security. The proposal is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that other exchanges offer a similar data product.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange intends to submit a separate rule filing to establish fees for Intraday Open-Close Data.

[6] *See https://datashop.cboe.com/.*

[7] Price information is not included in Intraday Open-Close Data because it cannot be provided within the time parameters necessary to generate the file.

[8] *See* Securities Exchange Act Release No. 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); *See also* Securities Exchange Act Release No. 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which may promote better informed trading throughout the trading day. Moreover, other exchanges offer a similar data product.[11]

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which as noted above, may promote better informed trading. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data on an intraday basis, and create and test trading models and analytical strategies. The Exchange believes Intraday Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

[11] *See* supra note 8.

Moreover, other exchanges also off a substantially identical data product.[12] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline (''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. PHOTO and NOTO provide substantially the same information as that included in the proposed Intraday Open-Close Data product. Further, like the proposed product, the data is provided to subscribers cumulatively every 10 minutes and is available to subscribers within five minutes of the conclusion of each 10 minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[13] The Exchange is proposing to introduce Intraday Open-Close Data in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least two other U.S. options exchanges offer a market data product that is similar to the Intraday Open-Close Data.[14] As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6)[16] thereunder.

[12] *Id.*

[13] *Id.*

[14] *Id.*

The Exchange has asked the Commission to waive the 30-day operative delay.[17] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Specifically, waiver of the operative delay will allow the Exchange to offer to investors without delay an optional historical data product that is substantially similar to products offered by other options exchanges. The proposal therefore does not present any novel issues and, accordingly, the Commission designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2020–036 on the subject line.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2020–036. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2020–036 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17561 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89500; File No. SR–NYSE–2020–66]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Rule 122

August 6, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 3, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 122 (Orders with More than One Broker). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, Rule 122 (Orders with More than One Floor Broker) provides that a member organization may not maintain orders with more than one Floor broker to purchase the same security at the same price. Because each Floor broker is a separate Participant in a parity allocation,[4] Rule 122 prevents member organizations from circumventing the parity allocation rules to obtain preferential execution by splitting a single order among multiple Floor brokers.

Rule 122 currently contains an exception and the main purpose of the proposed amendment is to clarify this exception. The exception is: If the orders are not for the account of the same principal, then it is permissible for the member organization to maintain such orders with different Floor brokers. This exception reflects the Exchange's understanding that some member organizations, or customers of member organizations, have multiple trading desks that do not coordinate trading strategies and are separated by information barriers. In such circumstances, because there is no coordination between such trading desks, maintaining those separate orders with more than one Floor broker would not be circumventing the parity allocation rules. The proposed amendment to Rule 122 would add Commentary to add specificity about this exception with respect to both member organizations' proprietary orders and orders that member organizations represent on an agency basis for customers.

Both member organizations and the customers of member organizations may consist of multiple trading units that are separated by information barriers that restrict the trading units from coordinating trading strategies, sharing capital, and sharing profits and losses. The proposed amended rule would provide that, if a member organization has knowledge and can verify that it or its customer is organized in this way, the member organization may route orders for the same security at the same price from its independent units to more than one Floor broker in a manner that is consistent with Rule 122.

In addition, the Exchange proposes to amend the text of Rule 122 to remove certain obsolete language and to provide greater specificity to the rule text, without changing its meaning.

2. Proposed Changes to Text of Rule 122

The Exchange proposes to amend Rule 122 to remove certain obsolete language and to provide greater specificity to the rule text, without changing its meaning.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Rule 7.36(a)(5) (defining the term ''Floor Broker Participant'' to mean a Floor Broker trading license).

Because the text of current Rule 122 addresses two distinct topics, the Exchange proposes to reorganize the existing rule text into new subsections (a) and (b), which the Exchange believes will enhance comprehension of the rule.

The Exchange proposes that new subsection (a) would include the current first sentence of Rule 122. Because the term ''member'' refers to the natural person associated with a member organization who has been designated by such member organizations to effect transactions on the Floor of the Exchange, *e.g.,* a Floor broker,[5] and Floor brokers do not originate orders,[6] and because the term ''allied member'' no longer exists in Exchange rules,[7] the Exchange proposes to delete the extraneous language ''member'' and ''or any allied member therein.''

The Exchange further proposes to amend new subsection (a) to specify that the rule applies both to orders ''sent to''—as well as those ''maintained with''—more than one Floor broker, and to insert the word ''Floor'' before ''broker'' to enhance the clarity of the sentence. The Exchange also proposes to replace the phrase ''market orders or orders at the same price'' in new subsection (a) with the phrase ''orders that may execute at the same price,'' to specify that the rule applies to multiple orders of any resting order type that may execute at the same price.

The Exchange proposes that new subsection (b) would include the current second and third sentences of Rule 122, relating to how a Floor broker can represent an order that already has a portion transmitted to the Exchange Book. Because this text addresses a different topic than proposed Rule 122(a), the Exchange proposes to delete the extraneous ''However'' at the start of the first sentence of this new subsection. The Exchange also proposes to delete from new subsection (b) several phrases—including ''manually or from a hand-held terminal,'' ''in the auction market or via the Floor broker agency interest file,'' and ''as part of an auction market transaction or automatic execution''—because they are extraneous, use obsolete text, and are not necessary to a clear understanding of the rule. The Exchange believes that making these deletions will have no substantive effect on the meaning of subsection (b).

Finally, the Exchange proposes to delete from new subsection (b) several references to the ''Display Book® system,'' which is an obsolete system formerly used by the Exchange, and to replace them with references to the Exchange's current ''Exchange Book.''[8]

3. Proposed Rule Commentary

In addition to the proposed amendments to the rule text listed above, the Exchange proposes to amend Rule 122 by adding new Rule Commentary to provide greater specificity as to the rule's application and to enhance comprehension of the rule.

The Exchange proposes to add Rule Commentary .01 to specify that, for the purposes of Rule 122, sending to, maintaining with, or using ''more than one Floor broker'' would mean more than one Floor broker member organization, or two different individual Floor brokers at the same Floor broker member organization. This proposed rule text is not intended to add new functionality, but rather to add clarity regarding the current Rule text.

The Exchange proposes to add Rule Commentary .02 to provide more specificity as to when a member organization's own orders are not presumed to be for the account of the same principal. As proposed, for purposes of Rule 122, when a member organization uses more than one Floor broker, multiple orders originating from the member organization would be presumed not to be for the account of the same principal if each order is from a separate trading unit that is separated by information barriers or other barriers that restrict the trading unit from coordinating trading strategies, sharing capital, and sharing profits and losses with other trading units (an ''Independent Unit''), as defined in proposed Commentary .02(a). Proposed Rule Commentary .02(b) would require a member organization to have supervisory systems and written policies and procedures reasonably designed to ensure that it is not using more than one Floor broker for its orders that are for the account of the same principal.

Proposed Rule Commentary .03 would apply the same concepts to circumstances when a member organization uses more than one Floor broker for multiple orders that it represents on an agency basis. Proposed Rule Commentary .03(a) would specify that orders that the member organization represents on an agency basis from a single customer are presumed not to be for the account of the same principal if the member organization's customer maintains Independent Units and the orders are from Independent Units. Proposed Rule Commentary .03(b) would specify that if a member organization is representing a customer on an agency basis and uses more than one Floor broker for such customer, the member organization's written policies and procedures must be reasonably designed to ensure that the orders it receives from the customer are from Independent Units of the customer. The proposed Rule Commentary would specify that the member organization must: (1) Use reasonable diligence to know and retain the essential facts relating to the operation and supervision of its customer's information barriers to ensure there is a prohibition against the coordination of trading strategies and that there is in fact no coordination of trading strategies, and that the orders are from Independent Units (*see* proposed Rule Commentary .03(b)(1)); (2) review and document such reviews that the orders received from its customers originated from Independent Units (*see* proposed Rule Commentary .03(b)(2)); and (3) obtain an annual written representation, in a form acceptable to the Exchange, from each customer that such orders originate from Independent Units (*see* proposed Rule Commentary .03(b)(3)). The Exchange believes that, taken together, these measures will provide the member organization and the Exchange with reasonable assurance that the orders are not for the account of the same principal, and member organizations are operating in compliance with Rule 122.

The requirements of proposed Commentary .03(b) are not the first time that the Exchange has imposed obligations on its member organizations with respect to orders that they represent on an agency basis on behalf of their customers. For example, Rule 7.44(b)(6), relating to the Exchange's Retail Liquidity Program, provides that if the Retail Member Organization does not itself conduct a retail business but instead routes Retail Orders on behalf of another broker-dealer, the Retail Member Organization's supervisory procedures must be reasonably designed to ensure that the orders it receives from such other broker-dealer meet the definition of a Retail Order. That Rule further provides that to fulfill this supervisory requirement, the Retail Member Organization must obtain an annual written representation, in a form acceptable to the Exchange, from the broker-dealer sending the orders that the orders comply with Rule 7.44, and by monitoring whether Retail Order flow

[5] *See* Rule 2(a) (definition of the term ''member'').

[6] *See* Rule 112(a).

[7] *See* Securities Exchange Act Release No. 58549 (September 15, 2008), 73 FR 54444 (September 19, 2008) (SR–NYSE–2008–80) (Approval order).

[8] *See* Rule 1.1(k).

routed on behalf of such other broker-dealer meets the applicable requirements. Here, the proposed amended rule would require a similar supervisory obligation for member organizations to ensure that orders placed by their customers in fact originate from Independent Units.

Proposed Rule Commentary .04 would add that notwithstanding Commentary .02(a) and .03(a), that there is a presumption that orders are for the account of the same principal (*i.e.,* not from Independent Units) if the trading strategies are run by the same desk, group, employee(s), or portfolio manager(s); are otherwise overseen or supervised by the same desk, group, employee(s), or portfolio managers; or share capital or roll up to the same profit and loss center.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed rule will remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed Rule Commentary provides greater specificity around the ''account of the same principal'' exception already contained within Rule 122, by clarifying the meaning of ''sending to more than one Floor broker'' and defining the term ''Independent Units.'' In addition, by extending that exception to orders from Independent Units of a member organization's customers, the Exchange believes that the proposed rule change would address the reality of how such customers may be organized, thereby removing impediments to such firms' trading in the national market system.

Finally, the Exchange's proposal to make various non-substantive changes to the rule text—by adding subsection numbering, removing extraneous language, and removing references to the obsolete ''Display Book® system''—adds clarity and transparency to the Exchange's Rules and reduces potential investor confusion, which would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it merely provides greater specificity for the ''account of the same principal'' exception already contained in Rule 122, and extends that exception to member organizations' customers that are organized into Independent Units. The Exchange believes that the proposal would have a positive effect on competition, by removing the current requirement that such member organizations' customers must use only one Floor broker for orders for the same security that may execute at the same price, even though such orders do not threaten to circumvent the Exchange's parity allocation rules when they originate from Independent Units.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2020–66 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–66. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–66 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17563 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89491; File No. SR–ICC–2020–010]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the ICC Risk Management Model Description

August 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on July 29, 2020, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to make changes to ICC's Risk Management Model Description. These revisions do not require any changes to the ICC Clearing Rules (the ''Rules'').[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to revise its Risk Management Model Description in connection with its proposed launch of the clearing of credit default index swaptions (''Index Swaptions'').[4] ICC has previously filed with the Commission changes to certain other policies and procedures related to the clearing of Index Swaptions (the ''Swaption Rule Filings'').[5] As set out in the Swaption Rule Filings, ICC intends to adopt or amend certain related policies and procedures in preparation for the launch of clearing of Index Swaptions and does not intend to commence clearing of Index Swaptions until all such policies and procedures have been approved by the Commission or otherwise become effective. Accordingly, ICC proposes to make such changes to the Risk Management Model Description effective following the approval of all such policies and procedures and the completion of the ICC governance process surrounding the Index Swaptions product expansion.

As discussed in the Swaption Rule Filings, pursuant to an Index Swaption, one party (the ''Swaption Buyer'') has the right (but not the obligation) to cause the other party (the ''Swaption Seller'') to enter into an index credit default swap transaction at a pre-determined strike price on a specified expiration date on specified terms. In the case of Index Swaptions that would be cleared by ICC, the underlying index credit default swap would be limited to certain CDX and iTraxx Europe index credit default swaps that are accepted for clearing by ICC, and which would be automatically cleared by ICC upon exercise of the Index Swaption by the Swaption Buyer in accordance with its terms.

The proposed changes amend the Risk Management Model Description to incorporate a stochastic implied mean absolute deviation (''MAD'') feature in connection with the proposed launch of the clearing of Index Swaptions and make certain other minor clarification changes. The proposed amendments would modify Section VII of the Risk Management Model Description to add a subsection on stochastic implied MAD modeling. In the Swaption Rule Filings, ICC proposed to modify the integrated spread response component of the margin model to incorporate an options-implied credit spread distribution, which includes a scale parameter related to the MAD implied from swaption prices (''implied MAD'').[6] ICC proposes enhancements to its approach to feature a stochastic implied MAD, which presents a more advanced risk modeling technique for option instruments in rapidly changing market conditions and high-volatility market environments. Currently, the model assumes a static implied MAD formulation where the implied MAD scale does not change in response to the simulated underlying index levels.

Under the proposed changes, the risk methodology for clearing Index Swaptions would consider the risk arising from the joint fluctuations of the underlying index levels and the options implied MAD scales in proposed Subsection VII.3. ICC would identify and describe the distribution that the changes of the implied MAD scales associated with each option expiry follow. ICC would also discuss and provide the rationale for its selected parameter estimation approach. Specifically, ICC would set out how the distribution parameters are estimated for a set of implied MAD changes. The proposed changes further explain how ICC models the joint fluctuations of the underlying index levels and the options implied MAD scales. Proposed Figure 12 illustrates the simulation approach and is thus intended to replace Figure 11 in Subsection VII.2.2 that ICC proposes to remove. Relatedly, in Subsection VII.5.1.1 with respect to instrument profit/loss (''P/L'') estimations for Index Swaptions, ICC proposes to add reference to notations related to the stochastic implied MAD from proposed Subsection VII.3.

ICC also proposes other minor clarification changes to the Risk Management Model Description. ICC propose to reference the clearinghouse in Subsection III.6 when describing where certain data is obtained and to abbreviate a term in Subsection VI.2. Given the addition of Subsection VII.3, ICC proposes to renumber the subsections in Section VII accordingly. ICC further proposes clarifications to a formula and its notes in Subsection VII.5.1.2 regarding risk factor P/L estimations, including with respect to the description of an alternative option position P/L computation, subsequent risk estimations and the addition of certain payments to portfolio requirements.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[7] and the regulations thereunder applicable to it, including the applicable

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used but not defined herein have the meanings specified in the Rules.

[4] Index Swaptions are also referred to herein and in the Risk Management Model Description as ''index options'' or ''index CDS options'', or in similar terms.

[5] SEC Release No. 34–87297 (Oct. 15, 2019) (approval), 84 FR 56270 (Oct. 21, 2019) (SR–ICC–2019–007); SEC Release No. 34–89142 (June 24, 2020) (approval), 85 FR 39226 (June 30, 2020) (SR–ICC–2020–002); SEC Release No. 34–89072 (June 16, 2020) (notice), 85 FR 37483 (June 22, 2020) (SR–ICC–2020–008).

[6] SEC Release No. 34–89142 (June 24, 2020) (approval), 85 FR 39226 (June 30, 2020) (SR–ICC–2020–002).

[7] 15 U.S.C. 78q–1.

standards under Rule 17Ad–22.[8] In particular, Section 17A(b)(3)(F) of the Act[9] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest. The proposed rule change would enable a stochastic implied MAD feature in the Risk Management Model Description in connection with the proposed launch of the clearing of Index Swaptions. In contrast to the static implied MAD formulation where the implied MAD scale does not change in response to the simulated underlying index levels, the stochastic implied MAD approach considers the joint fluctuations of the underlying index levels and the options implied MAD scales in proposed Subsection VII.3. Such feature presents a more advanced risk modeling technique for option instruments in rapidly changing market conditions and high-volatility market environments. The proposed clarification changes would further ensure readability and transparency with respect to ICC's risk methodology and practices in the Risk Management Model Description to ensure that it remains up-to-date, clear, and transparent to support the effectiveness of ICC's risk management system. ICC's view, these changes will enhance its risk model and thus enhance its ability to manage the participant default risk, including with respect to Index Swaptions. The proposed rule change is therefore consistent with the prompt and accurate clearing and settlement of the contracts cleared by ICC, including Index Swaptions, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[10]

The amendments would also satisfy relevant requirements of Rule 17Ad–22.[11] Rule 17Ad–22(e)(2)(i), (iii), and (v)[12] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent; support the public interest requirements of Section 17A of the Act[13] applicable to clearing agencies, and the objectives of owners and participants; and specify clear and direct lines of responsibility. ICC's Risk Management Model Description clearly assigns and documents responsibility and accountability for risk decisions and requires consultation or approval from relevant parties. ICC determined to incorporate a stochastic implied MAD feature in the Risk Management Model Description in accordance with its governance process, which included review and/or approval by the ICC Risk Committee and Board of the determination to enable the stochastic implied MAD feature of the model and the corresponding changes to the Risk Management Model Description. In ICC's view, the proposed rule change continues to ensure that ICC maintains policies and procedures that are reasonably designed to provide for clear and transparent governance arrangements that support the public interest requirements of Section 17A of the Act[14] applicable to clearing agencies, and the objectives of owners and participants, and specify clear and direct lines of responsibility, consistent with Rule 17Ad–22(e)(2)(i), (iii), and (v).[15]

Rule 17Ad–22(e)(4)(ii)[16] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. As discussed above, ICC proposes to modify the Risk Management Model Description to add a subsection on stochastic implied MAD modeling. Under the proposed changes, the risk methodology for clearing Index Swaptions would consider the risk arising from the joint fluctuations of the underlying index levels and the options implied MAD scales. ICC believes that the proposed changes support and enhance its ability to manage its financial resources as such feature presents a more advanced risk modeling technique for option instruments in rapidly changing market conditions and high-volatility market environments. Additionally, the proposed clarification changes provide further clarity and transparency regarding ICC's risk management practices to strengthen the documentation surrounding ICC's risk methodology, including the incorporation of a reference to the clearinghouse in Subsection III.6 when describing where certain data is obtained and the clarifications to a formula and its notes in Subsection VII.5.1.2. As such, the proposed amendments would strengthen ICC's ability to maintain its financial resources and withstand the pressures of defaults, consistent with the requirements of Rule 17Ad–22(e)(4)(ii).[17]

Rule 17Ad–22(e)(6)(i)[18] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market. ICC proposes to modify the Initial Margin Methodology section of the Risk Management Model Description to enable a stochastic implied MAD feature of the model in connection with the clearing of Index Swaptions. As described above, this feature considers the relationship between the underlying index levels and the implied MAD scales and presents a more advanced risk modeling technique for option instruments in rapidly changing market conditions and high-volatility market environments. ICC believes that such feature enhances its margin methodology, which considers and produces margin levels commensurate with the risks and particular attributes of each relevant product, portfolio, and market, consistent with the requirements of Rule 17Ad–22(e)(6)(i).[19]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. The proposed rule change would amend the Risk Management Model Description to add

[8] 17 CFR 240.17Ad–22.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] *Id.*

[11] 17 CFR 240.17Ad–22.

[12] 17 CFR 240.17Ad–22(e)(2)(i), (iii), and (v).

[13] 15 U.S.C. 78q–1.

[14] *Id.*

[15] 17 CFR 240.17Ad–22(e)(2)(i), (iii), and (v).

[16] 17 CFR 240.17Ad–22(e)(4)(ii).

[17] *Id.*

[18] 17 CFR 240.17Ad–22(e)(6)(i).

[19] *Id.*

a subsection on stochastic implied MAD modeling in connection with the proposed launch of the clearing of Index Swaptions and make certain other minor clarification changes. The proposed rule change will apply uniformly across all market participants. ICC does not believe acceptance of Index Swaptions for clearing would adversely affect the trading markets for such contracts, and in fact acceptance of such contracts by ICC would provide market participants with the additional flexibility to have their Index Swaptions cleared. Acceptance of Index Swaptions for clearing will not, in ICC's view, adversely affect clearing of any other currently cleared product. ICC does not believe the amendments would adversely affect the ability of Participants, their customers or other market participants to continue to clear contracts, including CDS Contracts. ICC also does not believe the enhancements would adversely affect the cost of clearing or otherwise limit market participants' choices for selecting clearing services in Index Swaptions, credit default swaps or other products. Accordingly, ICC does not believe the amendments would impose any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2020–010 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2020–010. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2020–010 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17557 Filed 8–11–20; 8:45 am]

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[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89496; File No. SR–C2–2020–010]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Introduce a New Data Product To Be Known as Intraday Open-Close Data

August 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2020, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product to be known as Intraday Open-Close Data.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a new data product on C2 to be known as Intraday Open-Close Data, which will be available for purchase to C2 Trading Permit Holders (''TPHs'') and non-TPHs.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Intraday Open-Close Data available for purchase to TPHs and non-TPHs on the LiveVol DataShop website.[6]

Currently, the Exchange offers Open-Close Data, which is an end-of-day volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), price, and transaction type (opening or closing). The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Open-Close Data is proprietary C2 trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Now, the Exchange is proposing to offer an additional product, the Intraday Open-Close Data. The Intraday Open-Close Data will provide similar information to that of Open-Close Data, but will be produced and updated every 10 minutes during the trading day. Data is captured in ''snapshots'' taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10 minute period. For example, subscribers to the intraday product will receive the first calculation of intraday data by approximately 9:45 a.m. ET, which represents data captured from 9:30 a.m. to 9:40 a.m. Subscribers will receive the next update by 9:55 a.m., representing the data previously provided aggregated with data captured up to 9:50 a.m., and so forth. Each update will represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus will provide open-close data on an aggregate basis. The Intraday Open-Close Data will provide a volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), and transaction type (opening or closing). The customer and professional customer volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Intraday Open-Close Data is proprietary C2 trade data and does not include trade data from any other exchange. In contrast to the existing Open-Close Data product, the Intraday Open-Close Data will not provide execution price.[7]

The Exchange will establish a monthly subscriber fee for Intraday Open-Close Data by way of a separate proposed rule change, which the Exchange will submit in connection with the launch of the Intraday Open-Close market data product.

The Exchange anticipates a wide variety of market participants to purchase Intraday Open-Close Data, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed Open-Close Data product may also provide helpful trading information regarding investor sentiment that may allow market participants to make better trading decisions throughout the day and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on C2. For example, intraday open data may allow a market participant to identify new interest or possible risks throughout the trading day, while intraday closing data may allow a market participant to identify fading interests in a security. The proposal is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that other exchanges offer a similar data product.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which may promote better informed trading throughout the trading day. Moreover, other exchanges offer a similar data product.[11]

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which as noted above, may promote better informed trading. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. Subscribers

[5] The Exchange intends to submit a separate rule filing to establish fees for Open-Close Data.

[6] *See https://datashop.cboe.com/.*

[7] Price information is not included in Intraday Open-Close Data because it cannot be provided within the time parameters necessary to generate the file.

[8] *See* Securities Exchange Act Release No. 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); *See also* Securities Exchange Act Release No. 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] *See* supra note 6.

to the data may be able to enhance their ability to analyze option trade and volume data on an intraday basis, and create and test trading models and analytical strategies. The Exchange believes Intraday Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

Moreover, other exchanges also off a substantially identical data product.[12] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline (''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. PHOTO and NOTO provide substantially the same information as that included in the proposed Intraday Open-Close Data product. Further, like the proposed product, the data is provided to subscribers cumulatively every 10 minutes and is available to subscribers within five minutes of the conclusion of each 10 minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[13] The Exchange is proposing to introduce Intraday Open-Close Data in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least two other U.S. options exchanges offer a market data product that is similar to the Intraday Open-Close Data.[14] As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[12] *Id.*

[13] *Id.*

[14] *Id.*

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) [16] thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay.[17] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Specifically, waiver of the operative delay will allow the Exchange to offer to investors without delay an optional historical data product that is substantially similar to products offered by other options exchanges. The proposal therefore does not present any novel issues and, accordingly, the Commission designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–C2–2020–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2020–010. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2020–010 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17559 Filed 8–11–20; 8:45 am]

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[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89502; File No. SR–PEARL–2020–03]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Establish Rules Governing the Trading of Equity Securities

August 6, 2020.

On January 24, 2020, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt rules to govern the trading of cash equities and establish an equities trading facility of the Exchange. The proposed rule change was published for comment in the **Federal Register** on February 12, 2020.[3] On March 25, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change, to May 12, 2020.[5] On May 8, 2020, the Exchange filed Amendment No. 1 to the proposed rule change.[6] On May 12, 2020, the Commission published notice of Amendment No. 1 and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[8] The Commission has received no comment letters on the proposed rule change, as modified by Amendment No. 1.

Section 19(b)(2) of the Act[9] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on February 12, 2020.[10] August 10, 2020 is 180 days from that date, and October 9, 2020 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendment No. 1, so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 1. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[11] designates August 24, 2020 as the date by which the Commission should either approve or disapprove the proposed rule change (File No. SR–PEARL–2020–03), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17564 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88132 (February 6, 2020), 85 FR 8053 (February 12, 2020) (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 88476 (March 25, 2020), 85 FR 17929 (March 31, 2020).

[6] In Amendment No. 1 the Exchange: (i) Deleted the definition of ''Equity Securities'' from proposed Exchange Rule 1901 and made corresponding changes throughout the proposed Exchange Rules to eliminate unnecessary confusion; (ii) substituted references to ''PEARL Equities'' with ''MIAX PEARL Equities'' throughout the proposed Exchange Rules; (iii) updated proposed Exchange Rule 2622 (Limit Up-Limit Down Plan and Trading Halts) regarding a Level 3 Market Decline to conform it to recent changes made by each of the national securities exchanges that trade equities and the Financial Industry Regulatory Authority (''FINRA''), and made a corresponding change to proposed Exchange Rule 2615 (Opening Process); and (iv) modified proposed Exchange Rule 2617(a)(4)(C) and (D) to account for the potential for orders to post and rest at prices that cross contra-side liquidity and also to correct a typographical error in proposed Exchange Rule 2617(a)(4)(D). Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-pearl-2020-03/srpearl202003-7168815-216600a.pdf.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 88859 (May 12, 2020), 85 FR 29759 (May 18, 2020).

[9] 15 U.S.C. 78s(b)(2).

[10] *See* Notice, *supra* note 3.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89499; File No. SR–NYSE–2020–55]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of a Proposed Rule Change To Amend Rules 7.36 and 7.37 Relating to Setter Priority and Allocation

August 6, 2020.

I. Introduction

On June 24, 2020, New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Rules 7.36 and 7.37 relating to Setter Priority and Allocation. The proposed rule change was published for comment in the **Federal Register** on June 30, 2020.[3] The Commission has received no comments on the proposed rule changes. The Commission is approving the proposed rule changes.

II. Description of the Proposed Rule Change

The Exchange proposes to modify the current operation of Setter Priority on the Exchange by changing the definition of orders eligible for Setter Priority and by changing the allocation that orders Setting Priority of contra-side Aggressing Orders.[4]

Currently, NYSE Rule 7.36(h) provides that an order may be assigned Setter Priority by (1) setting a new Best Bid or Offer (''BBO'') on the Exchange and (2) joining or setting the National Best Bid or Offer (''NBBO''), provided that such an order will not be eligible for Setter Priority if there is an odd-lot sized order with Setter Priority at that price.[5] Proposed NYSE Rule 7.36(h) would be amended to provide that an order is eligible for Setter Priority only if it sets a new NBBO.[6]

Currently, under NYSE Rule 7.37(b)(1), an order with Setter Priority equal to the BBO is eligible for a 15% allocation of an Aggressing Order

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89205 (June 30, 2020), 85 FR 40715 (June 30, 2020) (''Notice'').

[4] An ''Aggressing Order'' is defined as a buy (sell) order that is or becomes marketable against a sell (buy) interest on the Exchange Book. *See* NYSE Rule 7.36(a)(6).

[5] *See* Notice, *supra* note 3, 85 FR at 40716.

[6] *See id.* at 40715–16.

(rounded up to the next round lot size, or the full quantity of the Aggressing Order). Proposed NYSE Rule 7.37(b)(1) would be amended to provide that an order with Setter Priority equal to the BBO would be eligible to trade in full with the contra-side Aggressing Order.[7] The Exchange also represents that under the proposal, (1) if an Aggressing Order is greater in size than an order with Setter Priority, the order with Setter Priority would be executed in full and the remainder of the Aggressing Order would be allocated pursuant to NYSE Rule 7.37; and (2) if an Aggressing Order is smaller in size than an order with Setter Priority, the Aggressing Order would be executed in full, and the remainder of the order with Setter Priority would retain its Setter Priority status.[8]

III. Discussion and Commission Findings

After careful consideration, the Commission finds that the Exchange's proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges. In particular, the Commission finds that the Exchange's proposed rule change is consistent with Section 6(b)(5) of the Act,[9] which requires that the rules of an exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange asserts that assigning Setter Priority only to orders that establish a new NBBO, and allowing such orders to execute in full against incoming Aggressing Orders, would allow orders with Setter Priority to operate similarly to top-of-book orders at national securities exchanges with a price-time priority execution model and would thereby incentivize member organizations to route price-forming, liquidity-providing orders to the Exchange to the benefit of all market participants.[10] Because the Exchange's proposal would, unlike the current rule, require Setter Priority orders to set a new NBBO to be eligible for Setter Priority, and because the proposal would reward Setter Priority orders with a greater opportunity to trade against Aggressing Orders, the Commission believes that the proposed rule change is reasonably designed to incentivize member organizations to quote aggressively and improve the NBBO.

Based on the foregoing, the Commission therefore finds that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–NYSE–2020–55) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17562 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[7] The Exchange also proposes to delete existing text in NYSE Rule 7.37(b)(1)(C) pertaining to allocation when there are remaining quantities of an Aggressing Order and an order with Setter Priority. Under the proposal, either the order with Setter Priority, the Aggressing Order, or both orders would execute in full; thus, such an order book scenario would no longer be possible. *See id.* at 40716.

[8] *See id.* at 40715–16.

[9] 17 U.S.C. 78f(b)(5).

[10] *See* Notice, *supra* note 3, at 40717.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89497; File No. SR–CboeBZX–2020–059]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Introduce a New Data Product To Be Known As Intraday Open-Close Data

August 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product to be known as Intraday Open-Close Data. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a new data product on BZX to be known as Intraday Open-Close Data, which will be available for purchase to BZX Members (''Members'') and non-Members.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Intraday Open-Close Data available for purchase to Members and non-Members on the LiveVol DataShop website.[6] The Exchange also proposes to amend Exchange Rule 21.15(b) to provide that the Open-Close Data product will be available on an end-of-day basis and intraday basis.

Currently, the Exchange offers Open-Close Data, which is an end-of-day volume summary of trading activity on the Exchange at the option level by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange intends to submit a separate rule filing to establish fees for Intraday Open-Close Data.

[6] *See https://datashop.cboe.com/.*

origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), price, and transaction type (opening or closing). The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Open-Close Data is proprietary BZX trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Now, the Exchange is proposing to offer an additional product, the Intraday Open-Close Data. The Intraday Open-Close Data will provide similar information to that of Open-Close Data, but will be produced and updated every 10 minutes during the trading day. Data is captured in ''snapshots'' taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10 minute period. For example, subscribers to the intraday product will receive the first calculation of intraday data by approximately 9:45 a.m. ET, which represents data captured from 9:30 a.m. to 9:40 a.m. Subscribers will receive the next update by 9:55 a.m., representing the data previously provided aggregated with data captured through 9:50 a.m., and so forth. Each update will represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus will provide open-close data on an aggregate basis. The Intraday Open-Close Data will provide a volume summary of trading activity on the Exchange at the option level by origin (customer, professional customer, broker-dealer, and market maker), side of the market (buy or sell), and transaction type (opening or closing). The customer and professional customer volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The Intraday Open-Close Data is proprietary BZX trade data and does not include trade data from any other exchange. In contrast to the existing Open-Close Data product, the Intraday Open-Close Data will not provide execution price.[7]

A description of each market data product offered by the Exchange is described in Exchange Rule 21.15(b). The Exchange proposes to amend Rule 21.15(b)(5) to provide that Open-Close Data will be offered on an end-of-day and intraday basis.

The Exchange will establish a monthly subscriber fee for Intraday Open-Close Data by way of a separate proposed rule change, which the Exchange will submit in connection with the launch of the Intraday Open-Close market data product.

The Exchange anticipates a wide variety of market participants to purchase Intraday Open-Close Data, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed Open-Close Data product may also provide helpful trading information regarding investor sentiment that may allow market participants to make better trading decisions throughout the day and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on BZX. For example, intraday open data may allow a market participant to identify new interest or possible risk throughout the trading day, while intraday closing data may allow a market participant to identify fading interests in a security. The proposal is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that other exchanges offer a similar data product.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which may promote better informed trading throughout the trading day. Moreover, other exchanges offer a similar data product.[11]

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Intraday Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Intraday Open-Close Data. The proposed rule change would benefit investors by providing access to the Intraday Open-Close Data, which as noted above, may promote better informed trading. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data on an intraday basis, and create and test trading models and analytical strategies. The Exchange believes Intraday Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

Moreover, other exchanges also off a substantially identical data product.[12] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline

[7] Price information is not included in Intraday Open-Close Data because it cannot be provided within the time parameters necessary to generate the file.

[8] *See* Securities Exchange Act Release No. 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); *See also* Securities Exchange Act Release No. 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] *See* Supra note 8.

[12] *Id.*

(''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. PHOTO and NOTO provide substantially the same information as that included in the proposed Intraday Open-Close Data product. Further, like the proposed product, the data is provided to subscribers cumulatively every 10 minutes and is available to subscribers within five minutes of the conclusion of each 10 minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[13] The Exchange is proposing to introduce Intraday Open-Close Data in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least two other U.S. options exchanges offer a market data product that is similar to the Intraday Open-Close Data.[14] As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6)[16] thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay.[17] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Specifically, waiver of the operative delay will allow the Exchange to offer to investors without delay an optional historical data product that is substantially similar to products offered by other options exchanges. The proposal therefore does not present any novel issues and, accordingly, the Commission designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2020–059 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–059. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–059 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of rading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier

Assistant Secretary.

[FR Doc. 2020–17560 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[13] *Id.*

[14] *Id.*

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89490; File No. SR–NYSEAMER–2020–61]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the NYSE American Options Fee Schedule

August 6, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

notice is hereby given that, on August 3, 2020, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Options Fee Schedule (''Fee Schedule'') regarding the Professional Step-Up Incentive program. The Exchange proposes to implement the fee change effective August 3, 2020. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule regarding the Professional Step-Up Incentive program.

The Exchange proposes to implement the rule change on August 3, 2020.

Background

The Exchange has established various pricing incentives designed to encourage increased Electronic volume executed on the Exchange, including (but not limited to) the American Customer Engagement (''ACE'') Program, which provides credit on certain Customer executions, and the Professional Step-Up Incentive program (the ''Step-Up Incentive'').[4]

The Step-Up Incentive is a four-tier program—Tiers A–D—that offers discounted rates on monthly Professional volume as well as certain credits on Customer Electronic volume to ATP Holders that increase their Professional volume (excluding Strategy Executions, CUBE Auctions, and QCC Transactions) by specified percentages of Total Industry Customer equity and ETF option average daily volume (''TCADV''),[5] over their August 2019 volume, or in the case of new ATP Holders, above a base level of 10,000 ADV (the ''Qualifying Volume'').[6] ATP Holders that qualify for current Tiers C and D are also entitled to credits on their monthly Customer Electronic volume at the same rate as participants that achieve Tier 1 in the ACE Program.[7]

The Exchange proposes to simplify the Step-Up Incentive, which is voluntary, by removing two of the four tiers. In doing so, the Exchange has determined that it no longer seeks to provide a financial incentive for minimal increases to an ATP Holder's base volume levels and therefore proposes to increase the qualifying volume that would be required for the Step-Up Incentive's lower tier. The Exchange believes that the modified incentive program would still encourage ATP Holders to direct order flow to the Exchange, particularly given the high level of options trading in 2020, which additional liquidity benefits all markets participants on the Exchange.

Proposed Rule Change

Professional Step-Up Incentive

The Exchange is proposing to reduce the number of Step-Up Incentive Tiers from four to two by eliminating current Tiers A and C and renaming the remaining Tiers B and D as proposed Tiers A and B, respectively.[8] The Exchange also proposes to raise the qualification for the new Tier A (existing Tier B) from 0.08% of TCADV to 0.12% of TCADV. The proposed rule change is shown in the table below, with to-be-deleted text in brackets and proposed (new) text underscored.[9]

PROFESSIONAL STEP-UP INCENTIVE

	Qualifying volume as a % of TCADV	Per contract penny rate	Per contract non penny rate	ACE benefits
[Tier A]	[0.06]	[$0.45]	[$0.70]	[N/A].
Tier [B]*A*	[0.08]*0.12*	0.35	0.60	[N/A]*Tier 1.*
[Tier C]	[0.10]	[0.25]	[0.55]	[Tier 1].
Tier [D]*B*[1]	0.15	0.20	0.50	Tier 1.

[4] *See* Sections I.H and I.E. of the Fee Schedule (describing Professional Step-Up Incentive and ACE Program, respectively), available here: *https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf.*

[5] The term ''TCADV'' is defined in the Key Terms and Definitions Section of the Preface of the Fee Schedule, *see supra* note 4. TCADV includes Options Clearing Corporation (''OCC'') calculated Customer volume of all types, including Complex Order transactions and QCC transactions, in equity and ETF options.

[6] For purposes of this filing, ''Professional'' Electronic volume includes: Professional Customer, Broker Dealer, Non-NYSE American Options Market Maker, and Firm.

[7] *See* Fee Schedule, *supra* note 4.

[8] Proposed (and simply renamed) Tier B is substantively the same as existing Tier D and therefore ''ATP Holders that increase Qualifying Volume by 0.20% of TCADV and execute posted Professional volume (*i.e.,* that adds liquidity) of at least 0.10% of TCADV will receive a $0.03 per contract discount off the Tier B rates.'' *See* proposed Fee Schedule, Section I.H., note 1.

[9] *See* proposed Fee Schedule, Section I.H.

As shown in the table above, by achieving an increase in Qualifying Volume, benefits accrue to the ATP Holder. To put in context, assume an ATP Holder executed Electronic Professional volume in August 2019 totaling 9,000 ADV and, in July, the TCADV is 17,200,000. To qualify for the Step-Up Incentive program, that ATP Holder would need to execute Electronic Professional volume above its August 2019 volume that is at least 20,640 ADV (*i.e.,* 0.12% of TCADV) for new Tier A; 25,800 ADV (*i.e.,* 0.15% of TCADV) for new Tier B. If that same ATP Holder did not have August 2019 volume, it would have to execute at least this much volume above the 10,000 ADV base level.

The net result of the incentive program as modified is that proposed Tier A has a slightly higher minimum monthly volume requirement than the Tiers being deleted and a slightly higher (but still discounted) rate than existing Tier C. However, as further proposed, ATP Holders that qualify for new Tiers A and B would be eligible for ACE Tier 1 credits on certain Customer executions,[10] which should also encourage an increase in Customer volume to the benefit of all market participants.

The Exchange's fees are constrained by intermarket competition, as ATP Holders may direct their order flow to any of the 16 options exchanges, including those with similar incentive programs.[11] To address this competitive environment, the Exchange offers incentives, such as the voluntary Step-Up Incentive to encourage ATP Holders to consistently direct order flow (in particular Professional flow) to the Exchange. The Exchange believes that the proposal to streamline the Step-Up Incentive would simplify the incentive program while still offering discounted rates and credits. Although proposed Tier A of the modified Step-Up Incentive would require a higher minimum volume threshold for a lower discount (than existing, to-be-deleted, Tier C), the Exchange believes the incentive program would continue to incent ATP Holders to direct volume to the Exchange. In particular, proposed Tier A together with the existing requirements of new Tier B (current Tier D) continue to offer discounted rates coupled with ACE Tier 1 credits on certain Customer executions at a time where the Exchange has experience a significant increase in options trading. The Exchange believes the Step-Up Incentive, as modified, should continue to incent the consistent and concerted redirection of order flow to the Exchange by ATP Holders in exchange for better economics as provided by the incentive program (*i.e.,* enhanced discounts and credits), making it a more attractive venue for trading.

The Exchange notes that all market participants stand to benefit from increased Electronic Professional volume, which promotes market depth, facilitates tighter spreads and enhances price discovery, and may lead to a corresponding increase in order flow from other market participants, including those that do not participant in (or qualify for) the Step-Up Incentive (or the ACE) program.

The Exchange cannot predict with certainty whether any ATP Holders would avail themselves of the proposed rule change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[15] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in June 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[16]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The proposal to simplify the Step-Up Incentive by removing two of the four tiers is reasonable because participation in the incentive program is voluntary and the Exchange continues to offer discounted rates and credits. Although proposed Tier A of the modified Step-Up Incentive would require a higher minimum volume threshold for a lower discount (than existing, to-be-deleted, Tier C), the Exchange believes the incentive program would continue to incent ATP Holders to direct volume to the Exchange. In particular, proposed Tier A (which has a slightly higher minimum monthly volume requirement than the Tiers being deleted) together with the existing requirements of new Tier B (current Tier D) continue to offer discounted rates coupled with ACE Tier 1 credits on certain Customer executions at a time where the Exchange has experience a significant increase in options trading. The Exchange believes the Step-Up Incentive, as modified, should continue to incent the consistent and concerted redirection of order flow to the Exchange by ATP Holders in

[10] *See* Fee Schedule, Section I. A., *supra* note 4 (setting forth options transactions rates for Electronic Professional volume of $0.50 and $0.75 for Penny and Non-Penny issues respectively; except that Firm execution in Penny issues are charged $0.47 per contract).

[11] *See e.g.,* MIAX Options fee schedule, Section 1.a.iv, Professional Rebate Program, *available here, https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Options_Fee_Schedule_04012019.pdf* (setting forth per contract credits on volume submitted for the account of Public Customers that are not Priority Customers, Non-MIAX Market Makers, Non-Member Broker Dealers, and Firms (collectively, Professional for purposes of MIAX program), provided the Member achieves certain Professional volume increase percentage thresholds (set forth in the schedule) in the month relative to the fourth quarter of 2015).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[15] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/market-data/volume/default.jsp.*

[16] Based on OCC data, *see id.,* the Exchange's market share in equity-based options increased slightly from 8.20% for the month of June 2019 to 8.32% for the month of June 2020.

exchange for better economics as provided by the incentive program (*i.e.,* enhanced discounts and credits), making it a more attractive venue for trading.

The Exchange believes that the Step-Up Incentive, as modified, is still designed to encourage ATP Holders to increase the amount of Electronic Professional (and, given the ACE Tier 1 benefits, even Customer) volume directed to and executed on the Exchange. The Exchange notes that all market participants stand to benefit from increased Electronic Professional (and Customer) volume, which promotes market depth, facilitates tighter spreads and enhances price discovery, and may lead to a corresponding increase in order flow from other market participants, including those that do not participant in (or qualify for) the Step-Up Incentive (or the ACE) program.

The Exchange cannot predict with certainty whether any ATP Holders would avail themselves of the proposed rule change.

Finally, to the extent the proposed change attract greater volume and liquidity, the Exchange believes this would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The proposed rule change is designed to incent ATP Holders to direct liquidity to the Exchange in Electronic executions, similar to other exchange programs with competitive pricing programs, thereby promoting market depth, price discovery and improvement and enhancing order execution opportunities for market participants.[17]

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange and ATP Holders can opt to avail themselves of the Step-Up Incentive or not. Moreover, the proposal is designed to encourage ATP Holders to aggregate their executions—particularly Electronic Professional (and Customer)—at the Exchange as a primary execution venue. To the extent that the proposed change attracts more Professional (and Customer) Electronic volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory because the proposed modifications would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

Regarding the eliminated of Incentive Step-Up Tiers A and C, ATP Holders would continue to have the option of availing themselves of the still-reduced rates for Professional volume, as well as the ACE Tier 1 credits on certain Customer executions, that are available under proposed new Tier A and renamed Tier B.

The proposal is based on the amount and type of business transacted on the Exchange and ATP Holders are not obligated to try to achieve either of the incentive pricing options. Rather, the proposal is designed to continue to encourage these participants to utilize the Exchange as a primary trading venue (if they have not done so previously) or increase Electronic volume sent to the Exchange. To the extent that the proposed change attracts more executions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change—which continues to offer discounted rates and credits—would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [18]

Intramarket Competition. The proposed change is designed to attract additional order flow (particularly Professional, and Customer, volume) to the Exchange. The Exchange believes that the proposed modification to the Step-Up Incentive would continue to incent market participants to direct additional volume to the Exchange. Greater liquidity benefits all market participants on the Exchange. The proposed qualification Tiers would be available to all similarly-situated market participants that incur transaction fees on Electronic executions, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[19] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More

[17] *See, e.g., supra* note 11 (regarding MIAX Professional Rebate Program).

[18] *See* Reg NMS Adopting Release, *supra* note 14, at 37499.

[19] *See supra* note 15.

specifically, in June 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[20]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to encourage ATP Holders to direct trading interest to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar pricing incentives, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[21] of the Act and subparagraph (f)(2) of Rule 19b–4[22] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[23] of the Act to determine whether the proposed rule change should be approved or disapproved.

[20] Based on OCC data, *supra* note 16, the Exchange's market share in equity-based options was 8.20% for the month of June 2019 and 8.32% for the month of June 2020.

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2020–61 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2020–61. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2020–61 and should be submitted on or before September 2, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–17556 Filed 8–11–20; 8:45 am]

BILLING CODE 8011–01–P

[24] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 11179]

Advisory Committee on Historical Diplomatic Documentation; Notice of Virtual Open Meeting

The Advisory Committee on Historical Diplomatic Documentation will meet on September 14 in a virtual open session to discuss unclassified matters concerning the status of the *Foreign Relations* series.

The Committee will meet in open session from 10 a.m. until noon through a virtual platform TBD. Members of the public planning to attend the virtual meeting should RSVP to Julie Fort at *FortJL@state.gov.* RSVP and requests for reasonable accommodation should be sent not later than September 1, 2020. Instructions on how to join the virtual meeting will be provided upon receipt of RSVP.

Questions concerning the meeting should be directed to Adam M. Howard, Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State, Office of the Historian, Washington, DC 20372, *history@state.gov.*

Note that requests for reasonable accommodation received after September 1 will be considered but might not be possible to fulfill.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2020–17649 Filed 8–11–20; 8:45 am]

BILLING CODE 4710–34–P

DEPARTMENT OF STATE

[Public Notice 11115]

International Digital Economy and Telecommunication (IDET) Advisory Committee Solicitation of Applications for Membership

ACTION: Notice.

SUMMARY: The Deputy Assistant Secretary of State for International Communications and Information Policy, in the Bureau of Economic and Business Affairs is accepting

applications for membership on the International Digital Economy and Telecommunication (IDET) Advisory Committee, formerly known as the International Telecommunication Advisory Committee (ITAC).

DATES: Applications should be sent by email to *IDET@state.gov* by close of business on August 21, 2020.

FOR FURTHER INFORMATION CONTACT: Please contact the Designated Federal Officer (DFO) Daniel Oates at (202) 647–5205 or Lynnette Jackson at *IDET@state.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the IDET is to advise the Department of State with respect to, and provide strategic planning recommendations on, digital economy, digital connectivity, economic aspects of emerging digital technologies, telecommunications, and communication and information policy matters, including those related to the U.S. participation in the work of the International Telecommunication Union (ITU), the Organization of American States Inter-American Telecommunication Commission (CITEL), the Organization for Economic Cooperation and Development (OECD), the Asia Pacific Economic Cooperation (APEC) Forum Telecommunications and Information Working Group, the Group of Seven (G7), the Group of Twenty (G20) Digital Economy Task Force, and relevant standards setting bodies. Its Charter is accessible here: *https://www.state.gov/charter-of-the-united-states-international-digital-economy-and-telecommunication-advisory-committee/.*

Qualifications and Membership: IDET Members are appointed by the Deputy Assistant Secretary and must be U.S. citizens or legal permanent residents of the United States. The IDET charter calls for representative members; therefore, a prospective member must represent a company or organization. Solo members (who ''represent themselves'') will not be selected. To ensure diversity in advice, IDET membership will include not more than one representative from any affiliated agency or organization so long as the threshold of no fewer than 20 members is met. IDET members must be versed in the complexity of international communications and information policy issues and must be able to advise the Department of State on these matters. Members are expected to use their expertise and provide candid advice. Please note that IDET members will not be reimbursed for travel, per diem, nor other expenses incurred in connection with their duties as IDET members.

How to Apply: Applicants should email applications in response to this notice to *IDET@state.gov.* Applications must contain the following information: (1) Name of applicant; (2) citizenship of the applicant or residency status; (3) organizational affiliation and title; (4) mailing address; (5) work telephone number; (6) email address; (7) résumé; (8) brief statement of interest for IDET membership of no more than 300 words; and (9) confirmation that your organization or company expects you to represent their interests.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2020–17648 Filed 8–11–20; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Airport Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on request to release airport property for land disposal at the Liberal Mid-America Regional Airport (LBL), Liberal, Kansas.

SUMMARY: The FAA proposes to rule and invites public comment on the release and sale of land at the Liberal Mid-America Regional Airport (LBL), Liberal, Kansas.

DATES: Comments must be received on or before September 11, 2020.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106. In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Lynn Koehn, The Koehn Law Firm, L.L.C., 217 N Washington, Liberal, KS 67901, (620) 624–8158.

FOR FURTHER INFORMATION CONTACT: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106, (816) 329–2603, *amy.walter@faa.gov.*

The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release approximately 0.27 acres of airport property at the Liberal Mid-America Regional Airport (LBL) under the provisions of 49 U.S.C. 47107(h)(2). On July 28, 2020, the Airport Attorney requested from the FAA that approximately 0.27 acres of property be released for sale to Liberal New Iron & Metal, LLC. The FAA determined the request to release and sell property at Liberal Mid-America Regional Airport (LBL) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release and sale of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this Notice.

The following is a brief overview of the request:

Liberal Mid-America Regional Airport (LBL) is proposing the release and sale of a parcel of airport property, totaling 0.27 acres. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the release of land and surface rights at the Liberal Mid-America Regional Airport (LBL) from the conditions of the AIP Grant Agreement Grant Assurances, but retaining the mineral rights. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value and the property will continue to be used as an industrial park building site.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, request an appointment and inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Liberal Mid-America Regional Airport.

Issued in Kansas City, MO, on August 5, 2020.

James A. Johnson,

Director, FAA Central Region, Airports Division.

[FR Doc. 2020–17566 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. FAA–2020–61]

Petition for Exemption; Summary of Petition Received; Air Evac EMS Inc.

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2020.

ADDRESSES: Send comments identified by docket number FAA–2017–1253 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Quentin Flinn (202) 267–3873, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 5, 2020.

Brandon Roberts,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2017–1253.

Petitioner: Air Evac EMS Inc.

Section(s) of 14 CFR Affected: 91.411(b) & 91.413(c).

Description of Relief Sought: Air Evac EMS Inc., petitioned for an exemption to perform air traffic control (ATC) transponder tests and inspections and altimeter system and altimeter reporting equipment tests and inspections for its 14 CFR part 135 aircraft maintained under the Airbus manufacturers maintenance program.

[FR Doc. 2020–17646 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2020–64]

Petition for Exemption; Summary of Petition Received; Gulfstream Aerospace Corporation

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

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 1, 2020.

ADDRESSES: Send comments identified by docket number FAA–2020–0742 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael H. Harrison, AIR–673, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198, phone and fax 206–231–3368, email *Michael.Harrison@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Des Moines, Washington, on August 6, 2020.

James E. Wilborn,

Acting Manager, Transport Standards Branch.

Petition for Exemption

Docket No.: FAA–2020–0742.

Petitioner: Gulfstream Aerospace Corporation.

Section(s) of 14 CFR Affected: § 25.1322(c)(2).

Description of Relief Sought: Gulfstream Aerospace Corporation is seeking relief from 14 CFR 25.1322(c)(2), which requires transport category airplanes to have warning and

caution alerts that provide timely attention-getting cues to the flightcrew through at least two different senses by a combination of aural, visual, or tactile indications. Specifically, the petitioner is proposing to provide an amber indication for course deviation from a prescribed path, without a second sense or aural alert during Category II Instrument Approach Operations on its Model GVII–G500 and GVII–G600 airplanes.

[FR Doc. 2020–17583 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Travis County, Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), Department of Transportation.

ACTION: Federal Notice of Intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The FHWA, on behalf of TxDOT, is issuing this notice to advise the public that an EIS will be prepared for a proposed transportation project to construct two non-tolled managed lanes in each direction along Interstate Highway 35 (I–35) from US Highway 290 (US 290) East to US 290 West/State Highway (SH) 71, and add direct connectors at I–35/US 290 East, in Austin, Travis County, Texas (referred to as the Capital Express Central Project).

FOR FURTHER INFORMATION CONTACT: Adam Kaliszewski, P.E., Transportation Engineer, TxDOT Austin District, 7901 N I–35, Austin, TX 78753; Phone: (512) 832–7183; Email: *adam.kaliszewski@txdot.gov.*

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

TxDOT will prepare an EIS for proposed improvements to I–35 through the city of Austin, Texas. The project is anticipated to be approximately 8 miles long on I–35, from US 290 East to US 290 West/SH 71.

The EIS will evaluate a range of build alternatives and a no-build alternative. Possible alternatives include lowered sections of managed and general purpose lanes. Each build alternative would include various operational and safety enhancements that optimize the roadway footprint, and would reconstruct ramps, bridges, and intersections; improve frontage roads; enhance bicycle and pedestrian accommodations; accommodate transit routes; and add direct connectors at I–35/US 290 East.

TxDOT will issue a single Final Environmental Impact Statement and Record of Decision document pursuant to 23 U.S.C. 139(n)(2), unless TxDOT determines statutory criteria or practicability considerations preclude issuance of a combined document.

In accordance with 23 U.S.C. 139, cooperating agencies, participating agencies, and the public will be given an opportunity for continued input on project development. A public scoping meeting is planned for Fall/Winter 2020. Event details are still being determined. An agency scoping meeting will also be held with participating and cooperating agencies. The agency and public scoping meetings will provide an opportunity for the participating/cooperating agencies and public to review and comment on the draft coordination plan, the schedule, and the project purpose and need, as well as providing the opportunity to discuss the range of alternatives and methodologies and level of detail for analyzing alternatives. In addition to the agency and public scoping meetings, public meetings and comprehensive stakeholder engagement will take place and a public hearing will be held. Public notice will be given of the time and place of the meetings and hearing.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2020–17574 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1999–6480; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2008–0106; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2011–0379; FMCSA–2012–0104; FMCSA–2012–0159; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0007; FMCSA–2015–0348; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0029; FMCSA–2016–0030; FMCSA–2018–0012; FMCSA–2018–0014]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 32 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–1999–6480; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2008–0106; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2011–0379; FMCSA–2012–0104; FMCSA–2012–0159; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0007; FMCSA–2015–0348; FMCSA–2016–0027; FMCSA–2016–0028;

FMCSA–2016–0029; FMCSA–2016–0030; FMCSA–2018–0012; FMCSA–2018–0014, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Docket Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On June 30, 2020, FMCSA published a notice announcing its decision to renew exemptions for 32 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (85 FR 39265). The public comment period ended on July 30, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 32 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

As of August 1, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 15 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (64 FR 68195; 65 FR 20251; 67 FR 17102; 69 FR 17267; 71 FR 16410; 71 FR 32183; 71 FR 41310; 73 FR 28186; 73 FR 36955; 75 FR 25917; 75 FR 27623; 75 FR 36779; 75 FR 39729; 77 FR 15184; 77 FR 27847; 77 FR 27850; 77 FR 29447; 77 FR 36338; 77 FR 38384; 77 FR 38386; 79 FR 10611; 79 FR 14571; 79 FR 22003; 79 FR 27043; 79 FR 27681; 79 FR 28588; 79 FR 29495; 79 FR 35218; 79 FR 35220; 79 FR 38649; 81 FR 6573; 81 FR 26305; 81 FR 28136; 81 FR 28138; 81 FR 39320; 81 FR 42054; 81 FR 66720; 81 FR 66722; 81 FR 66724; 81 FR 77173; 81 FR 90050; 81 FR 91239; 81 FR 96196; 83 FR 6919; 83 FR 24146; 83 FR 28320; 83 FR 28325; 83 FR 28332; 83 FR 34661; 83 FR 45749):

Daniel A. Bahm (FL)
Felix Barajas Ramirez (IL)
William C. Dempsey, Jr. (MA)
Miguel H. Espinoza (CA)
Troy L. Hargrave (MO)
Timothy B. Hummel (KY)
Darius R. Law (FL)
Randall L. Mathis (AL)
Cody N. McDonnell (OR)
Hassan Ourahou (KY)
Tommy L. Ray, Jr. (AL)
Elston L. Taylor (VA)
Steve A. Taylor (NC)
Ronald L. Walker (FL)
James C. Wechsler (OR)

The drivers were included in docket numbers FMCSA–1999–6480; FMCSA–2006–24783; FMCSA–2010–0082; FMCSA–2011–0379; FMCSA–2012–0104; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2015–0348; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0029; FMCSA–2018–0012. Their exemptions are applicable as of August 1, 2020, and will expire on August 1, 2022.

As of August 6, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 36336; 77 FR 46795; 79 FR 38661; 81 FR 90050; 83 FR 34661):

Jay Turner (OH)

The driver was included in docket number FMCSA–2012–0059. The exemption is applicable as of August 6, 2020, and will expire on August 6, 2022.

As of August 8, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 38659; 79 FR 53514; 81 FR 90050; 83 FR 34661):

Jimmy A. Baker (TX); David L. Miller (OH); and Cory J. Tivnan (WA)

The drivers were included in docket number FMCSA–2014–0007. Their exemptions are applicable as of August 8, 2020, and will expire on August 8, 2022.

As of August 9, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (75 FR 34210; 75 FR 47888; 77 FR 40945; 79 FR 40945; 81 FR 90050; 83 FR 34661):

Mark S. Berkheimer (PA); Michael A. Jabro (MI); and Buddy W. Myrick (TX)

The drivers were included in docket number FMCSA–2010–0114. Their exemptions are applicable as of August 9, 2020, and will expire on August 9, 2022.

As of August 12, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (81 FR 45214; 81 FR 66726; 83 FR 34661):

Roger S. Orr (IA) and Keith R. Tyler (NC)

The drivers were included in docket number FMCSA–2018–0014. Their exemptions are applicable as of August 12, 2020, and will expire on August 12, 2022.

As of August 17, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (83 FR 33292; 83 FR 54644):

Joseph P. Markley (PA) and Curtis C. Williams (MO)

The drivers were included in docket number FMCSA–2018–0014. Their exemptions are applicable as of August 17, 2020, and will expire on August 17, 2022.

As of August 18, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following six individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for

interstate CMV drivers (71 FR 14567; 71 FR 30228; 73 FR 28187; 73 FR 35197; 73 FR 35199; 73 FR 35200; 73 FR 35201; 73 FR 48275; 75 FR 44051; 77 FR 46153; 79 FR 46153; 81 FR 90050; 83 FR 34661):

Steven G. Harter (OR)
Robert W. McMillian (MA)
Ryan J. Reimann (WI)
Brandon J. See (IA)
Ricky L. Shepler (PA)
Nils S. Thornberg (OR)

The drivers were included in docket numbers FMCSA–2006–24015 and FMCSA–2008–0106. Their exemptions are applicable as of August 18, 2020, and will expire on August 18, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–17555 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0098]

Request for Comments on the Renewal of a Previously Approved Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information to be collected will be used to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before October 13, 2020.

ADDRESSES: You may submit comments [identified by Docket No. MARAD–2020–0098 through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Jackson, 202–366–0615, Office of Management and Administrative Services, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC, 20590.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 2133–0543.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Respondents: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: 6,000.

Estimated Number of Responses: 6,000.

Estimated Hours per Response: 10–120 minutes.

Annual Estimated Total Annual Burden Hours: 1,958.

Frequency of Response: Once.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

* * * * *

Dated: August 6, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–17592 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0097]

Request for Comments on the Approval of a Previously Approved Information Collection: Voluntary Intermodal Sealift Agreement (VISA)

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information to be collected will be used by MARAD and the U.S. Transportation Command, and its components, to assure the continued availability of commercial sealift resources to meet the Department of Defense (DOD) military requirements. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before October 13, 2020.

ADDRESSES: You may submit comments [identified by Docket No. MARAD–2020–0097] through one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.

• *Fax:* 1–202–493–2251.

• *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: William McDonald, 202–366–0688, Office of Sealift Support, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Voluntary Intermodal Sealift Agreement (VISA).

OMB Control Number: 2133–0532.

Type of Request: Renewal of a previously approved collection.

Abstract: The collection is in accordance with Section 708, Defense Production Act, 1950, as amended, under which participants agree to provide commercial sealift capacity and intermodal shipping services and systems necessary to meet national defense requirements. In order to meet national defense requirements, the government must assure the continued availability of commercial sealift resources. The information collection is needed by MARAD and the Department of Defense (DOD), including representatives from the U.S. Transportation Command, to evaluate and assess the applicants' eligibility for participation in the VISA program.

Respondents: Operators of qualified dry cargo vessels.

Affected Public: Business or other for profit.

Estimated Number of Respondents: 40.

Estimated Number of Responses: 40.

Estimated Hours per Response: 5.

Annual Estimated Total Annual Burden Hours: 200.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.93)

* * * * *

Dated: August 6, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–17593 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petitions for Exemption From the Federal Motor Vehicle Theft Prevention Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petitions for exemption.

SUMMARY: This document grants in full four manufacturers' petitions for exemption for four model lines from the Federal Motor Vehicle Theft Prevention Standard (Theft Prevention Standard) beginning in model year (MY) 2021. The manufacturers, vehicle lines, and model years are as follows: Ford Motor Company (Ford) for its Bronco Sport vehicle line beginning in MY 2021; Jaguar Land Rover North America LLC (Jaguar Land Rover) for its Jaguar I-Pace vehicle line beginning in MY 2021; American Honda Motor Co., Inc. (Honda) for its HR–V vehicle line beginning in MY 2021; and Volkswagen Group of America, Inc. (Volkswagen) for its ID.4 vehicle line beginning in MY 2021.

DATES: The exemptions granted by this notice are effective beginning with the 2021 model year.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy, and Consumer Programs, NHTSA, West Building, W43–439, NRM–310, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: Under 49 U.S.C. chapter 331, the Secretary of Transportation (and the National Highway Traffic Safety Administration (NHTSA) by delegation) is required to promulgate a theft prevention standard to provide for the identification of certain motor vehicles and their major replacement parts to impede motor vehicle theft. NHTSA promulgated regulations at Part 541 (Theft Prevention Standard) to require parts-marking for specified passenger motor vehicles and light trucks. Pursuant to 49 U.S.C. 33106, manufacturers that are subject to the parts-marking requirements may petition the Secretary of Transportation for an exemption for a line of passenger motor vehicles equipped as standard equipment with an anti-theft device that the Secretary decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements. In accordance with this statute, NHTSA promulgated 49 CFR part 543, which establishes the process through which manufacturers may seek an exemption from the Theft Prevention Standard.

49 CFR 543.5 provides general submission requirements for petitions and states that each manufacturer may petition NHTSA for an exemption of one vehicle line per model year. Among other requirements, manufacturers must identify whether the exemption is sought under section 543.6 or section 543.7. Under section 543.6, a manufacturer may request an exemption by providing specific information about the anti-theft device, its capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements. Section 543.7 permits a manufacturer to request an exemption under a more streamlined process if the vehicle line is equipped with an anti-theft device (an ''immobilizer'') as standard equipment that complies with one of the standards specified in that section.

Section 543.8 establishes requirements for processing petitions for exemption from the Theft Prevention Standard. As stated in section 543.8(a), NHTSA processes any complete exemption petition. If NHTSA receives an incomplete petition, NHTSA will notify the petitioner of the deficiencies. Once NHTSA receives a complete petition it will process it and, in accordance with section 543.8(b), will grant the petition if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541.

Section 543.8(c) requires NHTSA to issue its decision either to grant or to deny an exemption petition not later than 120 days after the date on which a complete petition is filed. If NHTSA does not make a decision within the 120-day period, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the

petition for the subsequent model year.[1] Exemptions granted under Part 543 apply only to the vehicle line or lines that are subject to the grant and are equipped with the antitheft device on which the line's exemption was based and is effective for the model year beginning after the model year in which NHTSA issues the notice of exemption, unless the notice of exemption specifies a later year.

Sections 543.8(f) and (g) apply to how NHTSA's decisions on petitions are to be made known. Under section 543.8(f), if the petition is sought under section 543.6, NHTSA publishes a notice of its decision to grant or deny the exemption petition in the **Federal Register** and notifies the petitioner in writing. Under section 543.8(g), if the petition is sought under section 543.7, NHTSA notifies the petitioner in writing of the agency's decision to grant or deny the exemption petition.

This grant of petitions for exemption considers the following manufacturers' petitions for the following model years: Ford Motor Company (Ford) for its Bronco Sport vehicle line beginning in MY 2021; Jaguar Land Rover North America LLC (Jaguar Land Rover) for its Jaguar I-Pace vehicle line beginning in MY 2021; American Honda Motor Co., Inc. (Honda) for its HR–V vehicle line beginning in MY 2021; and Volkswagen Group of America, Inc. (Volkswagen) for its ID.4 vehicle line beginning in MY 2021.

As explained below, the petitions for all four manufacturers' vehicle lines are granted under 49 U.S.C. 33106, which states that if the Secretary of Transportation (NHTSA, by delegation) does not make a decision about a petition within 120 days of the petition submission, the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year. Separately, based on the information provided in each manufacturer's petition, NHTSA has determined that the antitheft device to be placed on each line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard.

I. Petition Approval Under 49 U.S.C. 33106(d)

As outlined above, if NHTSA does not make a decision on a complete exemption petition within the 120-day period after the date that the petition was filed,[2] the petition shall be deemed to be approved and the manufacturer shall be exempt from the standard for the line covered by the petition for the subsequent model year.[3]

Each manufacturer covered in this notice submitted a petition for exemption to NHTSA more than 120 days prior to this decision. Although each petition is accordingly approved pursuant to 49 U.S.C. 33106(d), for continuity for manufacturers, because MY 2021 production is likely to begin 8 months prior to the start of this notice,[4] NHTSA evaluated the specific information provided by each manufacturer in accordance with the requirements in 49 CFR 543.6, *Petition: Specific content requirements.* Based on this information, NHTSA separately determined that the antitheft device to be placed on each line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard.

II. Specific Petition Content Requirements Under 49 CFR 543.6

Pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention,* the four manufacturers described below petitioned for their specified vehicle lines an exemption from the parts-marking requirements of the Theft Prevention Standard, beginning in MY 2021. Ford, Jaguar Land Rover, Honda, and Volkswagen petitioned under 49 CFR 543.6, *Petition: Specific content requirements,* which, as described above, requires manufacturers to provide specific information about the anti-theft device installed as standard equipment on all vehicles in the line for which an exemption is sought, the anti-theft device's capabilities, and the reasons the petitioner believes the device to be as effective at reducing and deterring theft as compliance with the parts-marking requirements.

More specifically, section 543.6(a)(1) requires petitions to include a statement that an antitheft device will be installed as standard equipment on all vehicles in the line for which the exemption is sought. Under section 543.6(a)(2), each petition must list each component in the antitheft system, and a diagram showing the location of each of those components within the vehicle. As required by section 543.6(a)(3), each petition must include an explanation of the means and process by which the device is activated and functions, including any aspect of the device designed to: (1) Facilitate or encourage its activation by motorists; (2) attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; (3) prevent defeating or circumventing the device by an unauthorized person attempting to enter a vehicle by means other than a key; (4) prevent the operation of a vehicle which an unauthorized person has entered using means other than a key; and (5) ensure the reliability and durability of the device.[5]

In addition to providing information about the antitheft device and its functionality, petitioners must also submit the reasons for the petitioner's belief that the antitheft device will be effective in reducing and deterring motor vehicle theft, including any theft data and other data that are available to the petitioner and form a basis for that belief,[6] and the reasons for the petitioner's belief that the agency should determine that the antitheft device is likely to be as effective as compliance with the parts-marking requirements of Part 541 in reducing and deterring motor vehicle theft, including any statistical data that are available to the petitioner and form the basis for the petitioner's belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of passenger motor vehicles of the same, or a similar, line which have parts marked in compliance with Part 541.[7]

The following sections describe each manufacturer's petition information provided pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention.* To the extent that specific information in a manufacturer's petition is subject to a properly filed confidentiality request, that information was not disclosed as part of this notice. *See* 49 CFR 512.20(a).

a. Ford

In a petition dated December 12, 2019, Ford requested an exemption from the parts-marking requirements of the Theft Prevention Standard for its Bronco Sport vehicle line beginning with MY 2021. Pursuant to section 543.6(a)(1), Ford stated that the antitheft device described in its petition—Intelligent

[1] 49 U.S.C. 33106(d).

[2] *See* 51 FR 706; 52 FR 33821. Since the interim final rule implementing the Theft Prevention Standard, NHTSA has interpreted the filing date as meaning the date on which NHTSA receives a manufacturer's *complete* petition.

[3] 49 U.S.C. 33106(d).

[4] 49 U.S.C. 33106(c).

[5] 49 CFR 543.6(a)(3).

[6] 49 CFR 543.6(a)(4).

[7] 49 CFR 543.6(a)(5).

Access with Push Button Start (IAwPB)—will be standard equipment on its Bronco Sport vehicle line produced for the U.S. beginning with MY 2021 and beyond. Ford also stated that on its signature trim level models it will offer phone as key (Paak) feature via the LincolnWay app that can be used when paired with a smart phone instead of using a key fob to lock/unlock or remotely start/shutdown the vehicle.

In accordance with section 543.6(a)(2), Ford provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for its Bronco Sport vehicle line. Under section 543.6(a)(3), Ford described the IAwPB system as a passive, electronic engine immobilizer device that uses encrypted transponder technology. Key components of the IAwPB device will include an Intelligent Access electronic Push-Button Start key fob, keyless ignition system, radio transceiver module, body control module (BCM), powertrain control module (PCM), anti-lock braking system module (ABS) and an embedded secure modem (for Paak feature). Ford further stated that its Bronco Sport vehicle line will also be offered with a perimeter alarm system as standard equipment which will activate a visible and audible alarm whenever unauthorized access is attempted. Some additional features of the antitheft device include: Encrypted communication between the transponder, BCM control function and the PCM; ''virtually impossible'' key duplication; and shared security data between the body control module/remote function actuator and the powertrain control module.

Ford also provided information on the reliability and durability of its proposed device. To ensure reliability and durability of its device, Ford stated that it conducted tests on the antitheft device which complied with its own specific standards. Additionally, Ford stated that its antitheft device has no moving parts (*i.e.,* BCM, PCM, and electrical components) to perform system functions, which eliminate the possibility of physical damage or deterioration from normal use; and mechanically overriding the device to start the vehicle is also impossible. In further addressing the reliability and durability of its device, Ford stated that its Bronco Sport vehicle line will also be equipped with several other standard antitheft features common to Ford vehicles, (*i.e.,* hood release located inside the vehicle, counterfeit resistant VIN labels, secondary VINs, and cabin accessibility only with the use of a valid key fob).

Ford also stated that its system is automatically activated when the ''StartStop'' button is pressed, shutting off the engine. Ford stated that the device is deactivated when a start sequence is completed and engine start is successful. Ford further stated that the vehicle engine can only be started when the key is present in the vehicle and the ''StartStop'' button inside the vehicle is pressed. Ford stated that when the ''StartStop'' button is pressed, the transceiver module will read a key code and transmit an encrypted message to the control module to determine key validity and engine start by sending a separate encrypted message to the BCM and the PCM. The powertrain will function only if the key code matches the unique identification key code previously programmed into the BCM. Ford stated that the two modules must be matched together in order for the vehicle to start. If the codes do not match, the powertrain engine starter, spark, and fuel will be disabled. Ford further stated that any attempt to operate the vehicle without transmission of the correct code to the electronic control (*i.e.,* short circuiting the ''StartStop'' button) module will be ineffective.

Ford stated that its anti-theft system was introduced on all MY 1996 Ford Mustang GT and Cobra models as well as other selected models. Ford also stated that on its 1997 models, the installation of its antitheft device was extended to the entire Ford Mustang vehicle line as standard equipment and that according to the National Insurance Crime Bureau (NICB) theft statistics, MY 1997 Mustangs installed with the antitheft device showed a 70% reduction in theft rate compared to its MY 1995 Mustangs without an antitheft device.

Ford further stated that the proposed antitheft device is very similar to the system that was offered on its MY 2020 Lincoln Corsair vehicle line. The Lincoln Corsair vehicle line was granted a parts-marking exemption by NHTSA (84 FR 10890, March 22, 2019) beginning with its MY 2020 vehicles.

b. Jaguar Land Rover

In a petition dated November 26, 2019, Jaguar Land Rover requested an exemption from the parts-marking requirements of the Theft Prevention Standard for its Jaguar I-Pace vehicle line beginning with MY 2021. Pursuant to section 543.6(a)(1), Jaguar Land Rover stated that the antitheft device described in its petition—a passive, transponder-based, electronic engine immobilizer device—will be standard equipment on the Jaguar I-Pace model for MY 2021.

In accordance with section 543.6(a)(2), Jaguar Land Rover provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Jaguar I-Pace vehicle line. Under section 543.6(a)(3), Jaguar Land Rover described that key components of its antitheft device will include a Smart Key, powertrain control module (PCM), instrument cluster, body control module (BCM), remote frequency receiver (RFR), Immobilizer Antenna Unit (IAU), Remote Frequency Actuator (RFA), Security Horn and Vehicle Horn, Door Zone Modules (Passenger and Driver) (DMZs) and a Security Warning LED. Jaguar Land Rover stated that its antitheft device will also include a vehicle security system that includes an audible and visual perimeter alarm system as standard equipment on the entire vehicle line. The horn will sound and the vehicle's exterior lights will flash if unauthorized entry is attempted by opening the hood, doors, or luggage compartment. Jaguar Land Rover further stated that its perimeter alarm system can be armed with its Smart Key or programmed to be passively armed.

Jaguar Land Rover provided information on the reliability and durability of its proposed device as required by section 543.6(a)(3)(v). To ensure reliability and durability of the device, Jaguar Land Rover conducted tests based on its own specified standards. Jaguar Land Rover provided a detailed list of the tests conducted (*i.e.,* temperature and humidity cycling, high and low temperature cycling, mechanical shock, random vibration, thermal stress/shock tests, material resistance tests, dry heat, dust and fluid ingress tests). Jaguar Land Rover stated that it believes that its device is reliable and durable because it complied with specified requirements for each test. Additionally, Jaguar Land Rover stated that its key recognition sequence includes over a billion code combinations with encrypted data that are secure against duplication. Jaguar Land Rover further stated that the coded data transfer between modules use a unique secure identifier and public algorithm. Jaguar Land Rover also stated that since its Jaguar I-Pace vehicle line will utilize a push button vehicle ignition, it does not have a conventional mechanical key barrel, and therefore, a thief will have no means of forcibly bypassing the key-locking system.

Jaguar Land Rover stated that its immobilizer device is automatically activated when the Smart Key is removed from the vehicle. Jaguar Land Rover also stated that its Smart Key is programmed and synchronized to each

vehicle through an identification key code and a secret, randomly-generated code unique to each vehicle.

Jaguar Land Rover stated that there are three methods of antitheft device deactivation and engine starting. Method one consists of automatic detection of the Smart Key via a remote frequency challenge response sequence. Specifically, when the driver approaches the vehicle and pulls the driver's door handle following authentication of the correct Smart Key, the doors will unlock. When the ignition start button is pressed, the device searches to find and authenticate the Smart Key within the vehicle interior. If successful, this information is passed to the BCM via the Remote Function Actuator by coded data transfer. The BCM will pass the ''valid key'' status to the instrument cluster, via a coded data transfer and then send the ''key valid'' message code to the PCM initiating a coded data transfer and engine authorization to start. Method two consists of unlocking the vehicle with the Smart Key unlock button. As the driver approaches the vehicle, the Smart Key unlock button is pressed and the doors will unlock. Once the driver presses the ignition start button, the operation process is the same as method one. Method three involves using the emergency key blade. If the Smart Key has a discharged battery or is damaged, there is an emergency key blade that can be removed from the Smart Key and used to unlock the doors. When the ignition start button is pressed, the device searches to find and authenticate the Smart Key within the vehicle interior. If successful, the Smart Key needs to be docked. Once the Smart Key is docked/placed in the correct position, and the ignition start button is pressed again, the BCM and Smart key enter a coded data exchange via the Immobilizer Antenna Unit. The BCM then passes the valid key status to the instrument cluster, via the Immobilizer Antenna Unit and sends the key valid message to the PCM, which initiates a coded data transfer. If successful, engine starting is authorized.

Jaguar Land Rover stated that its immobilizer system on the Jaguar I-Pace is substantially similar to the antitheft devices using similar technology installed on the Jaguar F-Pace, Jaguar XJ, Jaguar F-Type, Jaguar XF, Jaguar XE, Land Rover Discovery Sport and the Land Rover Range Rover Evoque.

c. Honda

In a petition dated December 13, 2019, Honda requested an exemption from the parts-marking requirements of the Theft Prevention Standard for its HR–V vehicle line beginning with MY 2021. Pursuant to section 543.6(a)(1), Honda stated that the antitheft device described in its petition—a transponder-based ignition immobilizer system—will be installed as standard equipment on HR–V vehicles starting with MY 2021.

In accordance with section 543.6(a)(2), Honda provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the HR–V vehicle line. Honda stated that its vehicle line will offer a front-wheel drive and an all-wheel drive variation. Honda further stated that its MY 2021 HR–V vehicle line will be installed with a transponder-based, engine immobilizer antitheft device as standard equipment. More specifically, Honda stated that the HR–V vehicle line will offer two types of ignition systems, a ''smart entry push button start'' ignition system (''smart entry'') and a keyed ignition system with a key fob. Key components of the antitheft device will include a passive immobilizer, ''smart entry'' remote, powertrain control module (PCM) and an Immobilizer Entry System (IMOES). Honda further stated that its vehicle line will be installed with a vehicle security alarm system as standard equipment which will activate a visible and audible alarm whenever unauthorized access is attempted.

Honda provided information on the reliability and durability of its proposed device as required by section 543.6(a)(3)(v). To ensure reliability and durability of the device, Honda conducted tests based on its own specified standards. Honda provided a detailed list of the tests it used to validate the integrity, durability and reliability of its device and stated that the company believes that it follows a rigorous development process to ensure that its antitheft device will be reliable and robust for the life of the vehicle. Honda stated that its device does not require the presence of a ''smart entry'' remote battery to function nor does it have any moving parts (*i.e.,* the PCM, IMOES, ignition key, ''smart entry'' remote and the corresponding electrical components found within its own housing units), which it believes reduces the chance for deterioration and wear from normal use. Honda also stated that additional levels of reliability, durability and security will be accomplished because it will incorporate counterfeit resistant vehicle identification number (VIN) plates, secondary VINs, a hood release located inside the vehicle, and its smart entry remote will utilize rolling codes for the lock and unlock functions of its vehicles.

Honda further stated that its immobilizer device is always active without requiring any action from the vehicle operator as long as the matching smart entry remote is outside of the operating range and the engine is turned off. Deactivation occurs when a valid ''smart entry'' remote with matching codes is placed within operating range and the engine start/stop button is pushed to start the vehicle. Honda further states that if a ''smart entry'' remote without a matching code is placed inside the operating range and the engine start/stop button is pushed, the PCM will prevent fueling and starting of the engine. Additionally, an ignition immobilizer telltale indicator will begin flashing on the meter panel providing the status of the immobilizer device.

Honda stated that the audible and visible vehicle security alarm system installed on its HR–V vehicles will monitor any attempts of unauthorized entry and attract attention to an unauthorized person attempting to enter its vehicles without the use of a ''smart entry'' remote or its built-in mechanical door key. Specifically, Honda stated that whenever an attempt is made to open one of its vehicle doors, hood or trunk without using the ''smart entry'' remote or turning a key in the key cylinder to disarm the vehicle, the vehicle's horn will sound and its lights will flash. Honda stated that its vehicle security system is activated when all of the doors are locked and the hood and trunk are closed and locked. Honda further stated that its vehicle security system is deactivated by using the key fob buttons to unlock the vehicle doors or having the ''smart entry'' remote within operating range when the operator grabs either of the vehicle's front door handles.

Honda believes that installation of the antitheft immobilizer device as standard equipment reduces the vehicle theft rate by making conventional methods of theft obsolete, *i.e.,* punching out the steering column or hot-wiring the ignition. Additionally, Honda stated that the immobilizer device proposed for the 2021 HR–V is similar to the design offered on its Honda Civic, Honda Accord, Honda CR–V, Honda Pilot and Acura MDX, Honda Passport, and the Acura TLX vehicles which have been granted an exemption by the agency.

d. Volkswagen

In a petition dated December 20, 2019, Volkswagen requested an exemption from the parts-marking

requirements of the Theft Prevention Standard for its ID.4 beginning with MY 2021. Pursuant to section 543.6(a)(1), Volkswagen stated that the antitheft device described in its petition will be installed as standard equipment on the ID.4 vehicles starting with MY 2021.

In accordance with section 543.6(a)(2), Volkswagen provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for its ID.4 vehicle line.[8] Volkswagen stated that its MY 2021 ID.4 line will be installed with its fifth generation transponder-based electronic engine immobilizer antitheft device as standard equipment on the entire vehicle line. Key components of the antitheft device will include an immobilizer, power control unit (LSG1) in case of 4Motion all-wheel-drive system (LSG1 and LSG2), adapted ignition key (key fob) and an in-car application server 1 (ICAS1) with integrated gateway.

Volkswagen provided information on the reliability and durability of its proposed device as required by section 543.6(a)(3)(v). To ensure reliability and durability of the device, Volkswagen stated that the antitheft device has been tested for compliance with its corporate requirements, including those for electrical and electronic assemblies in motor vehicles related to performance requirements including electrical system temperature stability, mechanical integrity, electrical performance, electromagnetic compatibility (EMC), environmental compatibility and service life.

Volkswagen stated that its immobilizer device is aimed to actively incorporate the power control unit into the evaluation and monitoring process. Volkswagen also stated that activation of its immobilizer device occurs automatically after the engine is switched off. Deactivation of the immobilizer device occurs when the ignition is turned on or the key fob is recognized by the immobilizer control unit. Specifically, when turning on the ignition on/off switch, the key transponder sends a fixed code to the immobilizer control unit. If this is identified as the correct code, a variable code is generated in the immobilizer control unit and sent to the transponder. Volkswagen stated that a secret arithmetic process is then started according to a set of specific equations and that a new variable code is generated every time the immobilizer goes through the secret computing process. The results of the computing process are evaluated in the control unit and if verified, the vehicle key is acknowledged as correct. The engine control unit then sends a variable code to the immobilizer control unit for mutual identification. If all the data matches, the vehicle can be started.

In support of its belief that its antitheft device will be as or more effective in reducing and deterring vehicle theft than the parts-marking requirement, Volkswagen referenced the effectiveness of immobilizer devices installed on other vehicles for which NHTSA has granted exemptions. Specifically, Volkswagen referenced information from the Highway Loss Data Institute which showed that BMW vehicles experienced theft loss reductions resulting in a 73% decrease in relative claim frequency and a 78% lower average loss payment per claim for vehicles equipped with an immobilizer. Volkswagen also stated that the National Crime Information Center's (NCIC) theft data showed that there was a 70% reduction in theft experienced when comparing the MY 1987 Ford Mustang vehicle thefts (with immobilizers) to MY 1995 Ford Mustang vehicle thefts (without immobilizers).

III. Decision To Grant the Petitions

As discussed above, the petitions for all four manufacturers' vehicle lines are considered approved under 49 U.S.C. 33106. Separately, NHTSA believes, based on the supporting evidence submitted by each manufacturer, that the antitheft device described for each vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.8(b), the agency grants a petition for exemption from the parts-marking requirements of Part 541, either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that each manufacturer has provided adequate reasons for its belief that the antitheft device for each vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard. This conclusion is based on the information each manufacturer provided about its antitheft device.

As discussed in the notice, Petitions for Exemption From the Federal Motor Vehicle Theft Prevention Standard in the **Federal Register** of Monday, May 11, 2020,[9] NHTSA would like to reiterate that for manufacturers providing data to support their belief that a line of passenger motor vehicles equipped with the antitheft device is likely to have a theft rate equal to or less than that of the same, or similar, line which have parts marked in compliance with part 541, the agency is looking for the manufacturer to provide data comparing the subject vehicle line to that of a same, or similar line, pursuant to section 543.6(a)(5).[10]

The agency concludes that for Ford, Jaguar Land Rover, Honda and Volkswagen, each described device will provide the five types of performance features listed in section 543.6(a)(3): Promoting activation; attracting attention to the efforts of unauthorized persons to enter or operate a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR 543.8(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If any manufacturer listed in this notice decides not to use the exemption

[8] Volkswagen also stated that it will offer an audible and visible alarm as optional equipment on its ID.4 line. Per 49 U.S.C. 33106(b), manufacturers may petition NHTSA for an exemption "for a line of passenger motor vehicles equipped *as standard equipment* with an anti-theft device that [NHTSA] decides is likely to be as effective in reducing and deterring motor vehicle theft as compliance with" the Theft Prevention Standard (emphasis added). Per 49 U.S.C. 33106(a)(2), "standard equipment" means equipment already installed in a motor vehicle when it is delivered from the manufacturer and not an accessory or other item that the first purchaser customarily has the option to have installed. Therefore, for purposes of Volkswagen's petition, NHTSA is only considering the device equipped on the vehicle as standard equipment.

[9] 85 FR 27798 (May 11, 2020).

[10] This is because, to make a valid comparison, NHTSA must carefully choose two sets of vehicles that are as nearly similar as possible so that the agency can be reasonably certain that any differences or similarities in the theft rates of the two sets of vehicles can be attributed to the presence of an anti-theft device or parts marking and not to extraneous, confounding variables.

for its requested vehicle line, the manufacturer must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if any manufacturer listed in this notice wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.8(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, section 543.10(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in the exemption.''

The agency wishes to minimize the administrative burden that section 543.10(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be de minimis. Therefore, NHTSA suggests that if any manufacturer listed in this notice contemplates making any changes, the effects of which might be characterized as de minimis, it should consult the agency before preparing and submitting a petition to modify.

For the foregoing reasons, the agency hereby grants in full the following petitions for exemption for the following manufacturers' vehicle lines for the following model years: Ford Motor Company (Ford) for its Bronco Sport vehicle line beginning in MY 2021; Jaguar Land Rover North America LLC (Jaguar Land Rover) for its Jaguar I-Pace vehicle line beginning in MY 2021; American Honda Motor Co., Inc. (Honda) for its HR–V beginning in MY 2021; and Volkswagen Group of America, Inc. (Volkswagen) for its ID.4 beginning in MY 2021.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2020–17596 Filed 8–11–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modifications to Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before August 27, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on August 3, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
10880–M	Austin Powder Company	172.101(i), 173.35(b), 177.835(a), 177.848(g)(3).	To modify the special permit to authorize cargo vessel as an approved mode of transport. (modes 1, 3).
11110–M	United Parcel Service Co	171.8, 175.75	To modify the special permit to authorize additional airlines to use the permit. (mode 4).
11156–M	Orica USA Inc	173.212(b), 173.62(c)	To modify the special permit to authorize an alternative bag closure (glued seam). (modes 1, 3).
13220–M	Entegris, Inc	173.302, 173.302c	To modify the special permit to harmonize internal pressure limits and test pressures with UN Model Regulations, (modes 1, 2, 3).
15483–M	National Aeronautics And Space Administration.	173.302a	To modify the special permit to authorize a different 2.2 gas to be incorporated into the permit. (modes 1, 2, 3, 4, 5).
16274–M	Matheson Tri-gas, Inc	173.13(c)(2)(i), 173.13(c)(2)(ii), 173.13(c)(2)(iii).	To modify the special permit to authorize an additional Division 4.3 material. (modes 1, 4).
16318–M	Technical Chemical Company	173.304(d), 173.167(a)	To modify the special permit to authorize an additional 2.1 hazmat. (modes 1, 2, 3, 4, 5).
20588–M	Nantong Tank Container Co., Ltd	178.274(b)(1), 178.276(a)(2), 178.276(b)(1).	To modify the special permit to authorize a reduction in minimum design pressure and to increase the maximum water capacity. (modes 1, 2, 3).

[FR Doc. 2020–17600 Filed 8–11–20; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before September 11, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on August 4, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
		SPECIAL PERMITS DATA—Granted	
10922–M	Fiba Technologies, Inc	173.302(a), 180.205, 180.207(d)(1), 172.302(c)	To modify the special permit to authorize an additional outside diameter tube for a reference standard and its associated range of cylinder diameters that can be retested by UE.
11215–M	Orbital Sciences Corporation.	172.300, 172.600, 172.400, 172.500, 173.62, 175.75.	To modify the special permit to authorize additional hazmat contained in a new launch vehicle.
14656–M	Purepak Technology Corporation.	173.158(f)(3)	To modify the special permit to authorize an additional marking option to the outside of the package.
14849–M	Call2recycle, Inc	172.400, 172.102(c)(1), 172.200, 172.300, 173.159a(c)(2), 173.185(c)(1)(iii), 173.185(c)(1)(iv), 173.185(c)(1)(v), 173.185(c)(3), 172.303(a), 173.185(d).	To modify the special permit to authorize rail transportation, to allow batteries up to 300 Wh to be transported by vessel, and to clarify the lithium battery mark on the package.
20301–M	Tesla, Inc	172.101(j), 173.185(a)(1), 173.185(b)(3)(i), 173.185(b)(3)(ii).	To modify the special permit to authorize a new larger size prototype lithium battery.
20576–M	Cylinder Testing Solutions LLC.	172.203(a), 172.301(c), 180.205	To modify the special permit to authorize specific additional procedures for the testing of 3AL cylinders with labels under the clearcoat so they can continue to be tested using ultrasound, to add specific minimum wall specifications for testing 3AL cylinders and to update the update the authorized facilities under the SP.
20834–M	ECC Corrosion Inc	107.503(b), 107.503(c), 173.241, 173.242, 173.243, 178.345–1(d), 178.345–1(f), 178.345–2, 178.345–3, 178.345–4, 178.345–7, 180.405, 180.413.	To modify the special permit to authorize a redesign of the cargo tanks, to clarify the tank capacity and to modify the safety factor.
20901–N	Springfield Terminal Railway Co Inc.	174.14	To authorize the storage of liquid petroleum gas (LPG) on storage tracks in serving yards close to major LPG distribution facilities.
20907–M	Versum Materials, Inc	171.23(a), 171.23(a)(3)	To modify the special permit to authorize shipment of up to 60 cylinders a month.
20962–N	Portable Electric, Ltd	172.101(j), 173.185(b)	To authorize the transportation in commerce by cargo only aircraft of lithium-ion batteries that exceed the maximum weight allowed.
21022–N	Webasto Roof & Components Se.	172.101(j), 173.185(a)	To authorize the transportation in commerce of untested lithium ion batteries that exceed 35 kg by cargo-only aircraft.
21041–N	KLA Corporation	173.212, 173.213	To authorize the transportation in commerce of certain flammable solids in non-specification plywood boxes.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21051–N	Lab Vendor, LLC	173.196(a), 173.196(b), 173.199(a), 173.199(d), 178.603, 178.609(d).	To authorize the transportation of certain chemicals and cryogenically preserved (refrigerated and deep frozen) infectious, biological substances packaged in special packaging in a specially designed, dedicated refrigerated truck by highway.
21070–N	National Air Cargo Group, Inc.	172.101(j), 172.204(c)(3), 173.27(b)(2), 173.27(b)(3), 175.30(a)(1).	To authorize the transportation in commerce by cargo only aircraft of Class 1 explosives which are forbidden or exceed quantities presently authorized.
21076–N	Arkema Inc	173.22, 173.24, 173.24b(f)	To authorize the transportation of a UN T11 Isotank with a faulty pressure relief device filled with Ethyl Mercaptan to a repair facility.
21078–N	Saint Louis University	173.199	To authorize the transportation in commerce of 45 freezers containing Category B Infectious Substances.
21082–N	Department Of Resources Recycling And Recovery.	171.1	To authorize the transportation in commerce of certain hazardous materials in support of the recovery and relief operations from and within the fire disaster areas in California under conditions that may not meet the Hazardous Materials Regulations (HMR).
SPECIAL PERMITS DATA—Denied			
20974–N	PSC Custom LP	172.101(i), 173.302	To authorize the transportation in commerce of methane gas in MC 331 specification cargo tanks.
20990–N	PSC Custom LP	172.101(i)(3)	To authorize the transportation in commerce of methane gas in nurse tanks.
21032–N	Luxfer Inc	173.302a(a), 173.304a(a), 180.209	To authorize the manufacture, marking, sale and use of a non-DOT specification fully-wrapped carbon fiber composite cylinder with a seamless aluminum liner, to contain oxygen and other gases at 5000 psi. The cylinder will be designed, manufactured and tested in accordance with ISO 11119–2 with two extra tests defined by PHMSA.
21054–N	Siemens Energy, Inc	173.56(b)	To authorize the transportation in commerce of a Class 1 material under an alternate Class 1 designation.
SPECIAL PERMITS DATA—Withdrawn			
20391–M	Hexagon Purus LLC	173.301(f), 173.302(a)	To modify the special permit to authorize additional cylinders with a volume up to 3,000 liters.

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for New Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before September 11, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal

hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on August 4, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the Special Permits thereof
		SPECIAL PERMITS DATA	
21071–N	Norfolk Southern Railway Company.	174.85	To authorize the transportation in commerce of rail shipments without using buffer cars as required by 49 CFR 174.85. (mode 2)
21072–N	Isotek Systems, LLC	173.417(b)(1), 173.427(a)(3), 173.453(d).	To authorize the transportation in commerce of LSA–II radioactive material in alternative packaging. (mode 1)
21073–N	Bollore Logistics Germany Gmbh.	172.101(j), 172.300, 172.400, 173.301, 173.301, 173.302a(a)(1), 173.304a(a)(2).	To authorize the transportation in commerce of certain non-DOT specification containers containing certain Division 2.1, 2.2, 2.3 liquefied and compressed gases and other hazardous materials for use in specialty cooling applications such as satellites and military aircraft. (modes 1, 4)
21074–N	Zhejiang Meenyu Can Industry Co., Ltd.	173.304(a), 173.304(d)	To authorize the manufacture, mark, sale and use of a non-refillable, non-DOT specification inside metal container similar to a DOT specification 2Q. (modes 1, 2, 3)
21075–N	Aerojet Rocketdyne, Inc	172.200(a), 172.201(a)	To authorize the transportation in commerce of explosives between manufacturing facility and storage bunkers along approximately 5 miles of unpopulated low traffic highway without shipping papers. (mode 1)
21077–N	Kraton Corporation	173.31(d)(1)(ii)	To authorize the transportation in commerce of tank cars that have been leakage tested in lieu of visually inspected prior to shipping. (mode 2)
21080–N	Visuray LLC	173.222(c)(3)	To authorize the transportation in commerce of machinery/apparatus containing quantities of Division 2.2 gases in excess of what is authorized in 173.222. (modes 1, 2, 3, 4, 5)
21083–N	Alliant Techsystems Operations LLC.	172.200, 172.300, 172.604, 172.400, 172.500.	To authorize the transportation in commerce of hazardous materials a short distance between two facilities without utilizing hazard communication. (mode 1)
21084–N	Samsung SDI America, Inc	172.101(j)	To authorize the transportation in commerce of lithium batteries in excess of 35 kg by cargo-only aircraft. (mode 4)
21085–N	Omron Robotics And Safety Technologies, Inc.	172.101(j)	To authorize the transportation in commerce of lithium batteries exceeding 35 kg by cargo-only aircraft. (mode 4)
21086–N	Carmi Flavor And Fragrance Company, Inc.	173.120(a)	To authorize the transportation in commerce of flammable liquids below their flashpoint without being regulated as hazardous materials. (mode 1)
21087–N	Wates—Istanbul Genlesme Ve Hidrofor Tanklari Makine San. Ve Tic. As.	173.306(g)(1)	To authorize the transportation in commerce of water pumps charged with a compressed gas that vary from the required size of 173.306(g). (modes 1, 2, 3)
21088–N	Logbatt GmbH	173.24(g)	To authorize the manufacture, mark, sale, and use of packagings that vent for the purpose of transporting damaged, defective, and recalled batteries. (modes 1, 2, 3)
21089–N	Procyon-alpha Squared, Inc	172.200, 172.300, 172.600, 172.400.	To authorize the manufacture, mark, sale, and use of packaging for use with end-of-life/waste lithium ion cells, batteries and lithium ion cells and batteries contained in equipment shipped for recycling or disposal. (mode 1)
21090–N	Shijiazhuang Enric Gas Equipment Co., Ltd.	180.205	To authorize the use of UE testing for DOT 3AA, 3AAX, 3T and UN ISO 11120 cylinders in place of the internal visual inspection and the hydrostatic test method required in § 180.205. (modes 1, 2, 3)

[FR Doc. 2020–17603 Filed 8–11–20; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of a person who has been removed from the list of Specially Designated Nationals and Blocked Persons (SDN List). Their property and interests in property are no longer blocked, and U.S. persons are no longer generally prohibited from engaging in transactions with them.

DATES: See Supplementary Information section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treas.gov/ofac*).

Notice of OFAC Action(s)

The President identified the individuals in the Annex to Executive Order of 13620 of July 20, 2012, ''Taking Additional Steps to Address the National Emergency With Respect to Somalia,'' 77 FR 43483, 3 CFR, 2013 Comp., p. 281 (E.O. 13620). On July 10, 2020, the Director of OFAC determined that circumstances no longer warrant the inclusion of the following individual on the SDN List under this authority. This individual is no longer subject to the blocking provisions of Section 1(a) of E.O. 13620.

Individual

1. GHEBREAB, Yemane (a.k.a. GEBRE AB, Yemane; a.k.a. GEBREAB, Yemane; a.k.a. YOHANNES, Yemane Ghebreab W.), 12 Keren Street, Asmara, Eritrea; Tegadelti Street, Asmara, Eritrea; DOB 21 Jul 1951; POB Asmara, Eritrea; Passport D000901 (Eritrea); alt. Passport D001082 (Eritrea) (individual) [SOMALIA].

Dated: July 10, 2020.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–17585 Filed 8–11–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **Supplementary Information** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action

On August 7, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked pursuant to the relevant sanctions authority listed below.

Individual

SOULEYMANE, Bi Sidi (a.k.a. ABASS, Sidiki; a.k.a. ABBAS, Sidiki; a.k.a. BI SIDI, Souleymane; a.k.a. SIDIKI, Abbas; a.k.a. SOULEMAN, Bi Sidi; a.k.a. SOULEMANE, Bi Sidi; a.k.a. SOULIMANE, Sidiki Abass; a.k.a. ''Sidiki''), Central African Republic; DOB 20 Jul 1962; POB Bocaranga, Ouham-Pende prefecture, Central African Republic; nationality Central African Republic; alt. nationality Chad; alt. nationality Cameroon; Gender Male (individual) [CAR].

Designated pursuant to section 1(a)(ii)(A)(4) of Executive Order 13667 (E.O. 13667) of May 12, 2014, ''Blocking Property of Certain Persons Contributing to the Conflict in the Central African Republic,'' 79 FR 28387, 3 CFR 13667, for being responsible for or complicit in, or having engaged in, directly or indirectly, in or in relation to the Central African Republic, the targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law.

Dated: August 7, 2020.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–17625 Filed 8–11–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

IHS/THP Reimbursement Agreements Program—AI/AN Veterans Care Coordination

AGENCY: Department of Veterans Affairs.

ACTION: Notice of tribal consultation session.

SUMMARY: The Department of Veterans Affairs (VA), Veterans Health Administration (VHA) will facilitate a tribal consultation session regarding care coordination for veterans receiving care under the VA's Indian Health Service/Tribal Health Program (IHS/THP) Reimbursement Agreements Program. VA is seeking input on how we can ensure American Indian/Alaska Native (AI/AN) veterans, who need care beyond what is offered directly within IHS/THP facilities, are able to get that care seamlessly either in VA medical facilities or in the community. VA established the Healthcare Coordination Advisory Board, with participation from IHS and tribes, to assist in developing and implementing standardized processes for care coordination. This consultation session aims to discuss the approach developed from the Advisory Board meetings and receive attendees' feedback on the plans for implementation of care coordination activities.

Meeting Access Information: The virtual tribal consultation session will be held on Tuesday, August 25, 2020, from 3:30–5:00 p.m. (Eastern Standard Time). Participants can access the presentation by logging into the following:

https://vacctraining.adobeconnect.com/tribalconsultationihsthpreimbursementcarecoordinationplan/; for audio, please dial 1–800–767–1750, extension 85286. Participants will interact by submitting written comments/questions using the chat function during the presentation. Written comments may also be submitted to *tribalgovernmentconsultation@va.gov* before September 25, 2020, or by mail at Department of Veterans Affairs, Suite 915L, 810 Vermont Avenue NW, Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Please email Ms. Kara Hawthorne, IHS/THP Program Manager, VA Office of Community Care, at *Tribal.Agreements@va.gov,* or by telephone at 303–780–4826 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Utilizing the authorities found in 25 U.S.C. 1645(c), Sharing Arrangements with Federal Agencies, and 38 U.S.C. 8153, Sharing of Health-Care Resources, VA, IHS and Tribal Healthcare providers have created the IHS/THP Reimbursement Agreements Program. This program provides a means for IHS and THP health facilities to receive reimbursement from VA for direct care services provided to eligible AI/AN veterans. This tribal consultation session is seeking input from tribal governments regarding proposed

enhancement to care coordination efforts for eligible AI/AN veterans utilizing the Program when tribes cannot provide direct care services to veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Acting Chief of Staff, Department of Veterans Affairs, approved this document on July 29, 2020 for publication.

Luvenia Potts,

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

[FR Doc. 2020–17584 Filed 8–11–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411 et al.

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, and 419

[CMS–1736–P]

RIN 0938–AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021 based on our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this proposed rule would establish and update the Overall Hospital Quality Star Rating beginning with the CY 2021; remove certain restrictions on the expansion of physician-owned hospitals that qualify as ''high Medicaid facilities,'' and clarify that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; and add two new service categories to the OPD Prior Authorization Process.

DATES: To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on October 5, 2020.

ADDRESSES: In commenting, please refer to file code CMS–1736–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Nicole Hewitt via email *Nicole.Hewitt@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email *AuSha.Washington@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Nicole Hewitt via email *Nicole.Hewitt@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

Hospital Quality Star Rating Methodology, contact Annese Abdullah-Mclaughlin via email *Annese.Abdullah-Mclaughlin@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett via email *Allison.Bramlett@cms.hhs.gov*, or Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov* or, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology

APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov*.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services, contact Thomas Kessler via email at *Thomas.Kessler@cms.hhs.gov*.

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*. The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2021. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2021, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.6 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2021 would be approximately $83.9 billion, an increase of approximately $7.5 billion compared to estimated CY 2020 OPPS payments.

  We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Partial Hospitalization Update:* For CY 2021 OPPS/ASC proposed rule, CMS is proposing to maintain the unified rate structure established in CY 2017, with a single PHP APC for each provider type for days with three or more services per day. CMS is proposing to use the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing policy, using updated data for each provider type and a cost floor equal to the CY 2019 final geometric mean per diem cost for each provider type. Accordingly, CMS is proposing to calculate the CY 2021 PHP APC per diem rate for HB PHPs based on updated cost data and to calculate the rate for CMHCs based on the proposed cost floor.

- *Changes to the Inpatient Only (IPO) List:* For CY 2021, we propose to eliminate the IPO list over the course of three calendar years beginning with the removal of approximately 300 musculoskeletal-related services. We are also soliciting comments on whether three years is an appropriate time frame for transitioning to eliminate the IPO list; other services that are candidates for removal from the IPO list for CY 2021; and the sequence in which to remove additional clinical families and/or specific services from the IPO list in future rulemaking.

- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2021, we propose to continue a 2-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) referrals to Recovery Audit Contractors (RACs) and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on

January 1, 2021. We are also seeking comments on whether the 2-year exemption period continues to be appropriate, or if a longer or shorter period may be more warranted.

• 340B-*Acquired Drugs:* We propose for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. Similar to the 340B drug payment policy implemented in CY 2018, we are also proposing that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B payment policy for CY 2021 and subsequent years. Finally, we note that we propose in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

• *Comprehensive APCs:* For CY 2021, we propose to create two new comprehensive APCs (C–APCs). These new C–APCs include the following: C–APC 5378 (Level 8 Urology and Related Services) and C–APC 5465 (Level 5 Neurostimulator and Related Procedures). Adding these C–APCs would increase the total number of C–APCs to 69.

• *Device Pass-Through Payment Applications:* For CY 2021, we have received five applications for device pass-through payments that we discuss in this proposed rule. Two of these applications (CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope) have received preliminary approval for pass-through payment status through our quarterly review process. CMS is soliciting public comments on these five applications and will make a final determination on these applications in the CY 2021 OPPS/ASC final rule.

• *Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals:* For CY 2021 and subsequent years, we propose to change the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. We also propose that, for CY 2021 and subsequent years, direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services would include virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.

• *Cancer Hospital Payment Adjustment:* For CY 2021, we propose to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we propose that a target PCR of 0.89 would be used to determine the CY 2021 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2021, we propose to increase payment rates under the ASC payment system by 2.6 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 3.0 percent minus a proposed multifactor productivity adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2021 would be approximately 5.45 billion, an increase of approximately 160 million compared to estimated CY 2020 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2021, we propose to add eleven procedures to the ASC covered procedures list (CPL), including total hip arthroplasty (CPT 27130). Additionally, we propose two alternatives for changing the way procedures are added to the ASC CPL. Under the first alternative, we propose to establish a nomination process beginning in CY 2021 for procedures that would be added beginning in CY 2022 under which external stakeholders, such as professional specialty societies, would use suggested parameters to nominate procedures that can be safely performed in the ASC setting and meet all other regulatory standards. CMS would review nominated procedures and propose and finalize procedures to be added to the ASC CPL through annual rulemaking.

Under the second alternative proposal, we would revise the criteria for covered surgical procedures for the ASC payment system under 42 CFR 416.166, by keeping the general standards and eliminating five of the general exclusions. The revised criteria would result in the addition of approximately 270 surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list. Finally, we solicit comment on whether the conditions for coverage for ASCs should be revised if we adopt the second alternative proposal described above.

• *Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* For the Hospital OQR and ASCQR Programs, we propose to update and refine requirements to further meaningful measurement and reporting for quality of care provided in these outpatient settings while limiting compliance burden. We propose to revise and codify previously finalized administrative procedures and to propose and codify an expanded review and corrections process to further the programs' alignment while clarifying program requirements. We are not proposing any measure additions or removals for either program.

• *Overall Hospital Quality Star Ratings:* We propose to establish and update the methodology that would be used to calculate the Overall Hospital Quality Star Ratings beginning with 2021 and for subsequent years. CMS is proposing to, among other proposals, update and simplify how the ratings are calculated, reduce the total number of measure groups, and stratify the Readmission measure group based on the proportion of dual-eligible patients. These changes will simplify the methodology, and therefore, reduce provider burden, improve the predictability of the star ratings, and increase the comparability between hospital star ratings.

• *Addition of New Service Categories for Hospital Outpatient Department Prior Authorization Process:* We propose the addition of the following two categories of services to the prior authorization process beginning for dates of service on or after July 1, 2021: (1) Cervical fusion with disc removal and (2) implanted spinal neurostimulators.

• *Clinical Laboratory Date of Service (DOS) Policy:* We propose to exclude

cancer-related protein-based MAAAs, which are not generally performed in the HOPD setting, from the OPPS packaging policy and add them to the laboratory DOS provisions at § 414.510(b)(5).

- *Physician-Owned Hospitals:* We propose the (1) removal of unnecessary regulatory restrictions on high Medicaid facilities and (2) including beds in a physician-owned hospital's baseline consistent with state law.

3. Summary of Costs and Benefit

In sections XIX. and XX. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 55 in section XIX.B of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2021 compared to all estimated OPPS payments in CY 2020. We estimate that the policies in this proposed rule would result in a 2.5 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,628 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately 1.6 billion compared to CY 2020 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 1.3 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2021 IPPS proposed rule wage indexes would result in an estimated increase of 0.2 percent for urban hospitals under the OPPS and an estimated increase of 0.4 percent for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C. of this proposed rule.

c. Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2021 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we propose to implement the required reduction to the cancer hospital payment adjustment required by section 16002 of the 21st Century Cures Act for CY 2021, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2020, and therefore has no budget neutrality adjustment.

d. Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we propose to establish an OPD fee schedule increase factor of 2.6 percent and apply that increase factor to the conversion factor for CY 2021. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase of approximately 2.8 percent and that rural hospitals would experience an increase of 3.6 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience an increase of 3.5 percent, minor teaching hospitals would experience an increase of 3.2 percent, and major teaching hospitals would experience an increase of 1.6 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.7 percent in payments, while hospitals with government ownership would experience a decrease of 0.3 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 4.4 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2021 payment rates, compared to estimated CY 2020 payment rates, generally ranges between an increase of 2 and 5 percent, depending on the service, with some exceptions. We estimate the proposed impact of applying the hospital market basket update to ASC payment rates would increase payments by $160 million under the ASC payment system in CY 2021.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on

February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for covered ASC procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 19, 2018, for a 2-year period (84 FR 26117).

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 19, 2019. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, announce new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 19, 2019, meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 19, 2019 Panel meeting, namely APC assignments for certain CPT codes, a comprehensive APC for skin substitute products, a comprehensive APC for autologous hematopoietic stem cell transplantation, and packaging policies, were discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61148). For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *http://facadatabase.gov*.

F. Public Comments Received on the CY 2020 OPPS/ASC Final Rule With Comment Period

We received approximately 22 timely pieces of correspondence on the CY 2020 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 12, 2019 (84 FR 61142), most of which were outside of the scope of the final rule. In-scope comments related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments on topics that were open to comment and our responses to them will be set forth in various sections of the final rule with comment period under the appropriate subject-matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not

less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2021 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2021, and before January 1, 2022 (CY 2021), using the same basic methodology that we described in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61149), using updated CY 2019 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2021, we began with approximately 167 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2019, and before January 1, 2020, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 87 million final action claims to develop the proposed CY 2021 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to this proposed rule (which is available via the internet on the CMS website) includes the proposed list of bypass codes for CY 2021. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2019 and, therefore, includes codes that were in effect in CY 2019 and used for billing, but were deleted for CY 2020. We propose to retain these deleted bypass codes on the proposed CY 2021 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2021 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we propose to add for CY 2021 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2021, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2021 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2019 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2018. For the proposed CY 2021 OPPS payment rates, we used the set of claims processed during CY 2019. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2019 (the year of claims data we used to calculate the proposed CY 2021 OPPS payment rates) and updates to the NUBC 2019 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals used a less precise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while we recommended using two alternative allocation methods, ''direct assignment'' or ''dollar value,'' as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. Further, we finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use ''square feet'' as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning in CY 2018 with the sunset of the transition policy, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228 and 59229) and in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58831), we finalized a policy to extend the transition policy for 1 additional year and we continued to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs for the CY 2018 OPPS and the CY 2019 OPPS.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR

74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 1 demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

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TABLE 1: PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.6%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.1%
5524	Level 4 Imaging without Contrast	5.5%
5571	Level 1 Imaging with Contrast	6.7%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.1%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.9%
8007	MRI and MRA without Contrast Composite	7.0%
8008	MRI and MRA with Contrast Composite	7.3%

TABLE 2: PROPOSED CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0347	0.0491	0.0764	0.1016
Square Feet Only	0.0286	0.0444	0.0665	0.0928
Direct Assign	0.0472	0.0564	0.0935	0.1183
Dollar Value	0.0414	0.0553	0.0858	0.1128
Direct Assign and Dollar Value	0.0415	0.0555	0.0866	0.1131

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Our analysis shows that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 18.5 percent to 2,195 providers and the number of valid CT CCRs has increased by 16.3 percent to 2,275 providers. Table 1 displays the impact on proposed OPPS payment rates for CY 2021 if claims from providers that report using the ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a ''square feet'' cost allocation method as shown in Table 1.

We note that the CT and MRI cost center CCRs have been available for ratesetting since the CY 2014 OPPS in which we established the transition policy. Since the initial 4-year transition, we had extended the transition an additional 2 years to offer providers flexibility in applying cost allocation methodologies for CT and MRI cost centers other than ''square feet.'' In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), we finalized a 2-year phased-in approach, as suggested by some commenters, that applied 50 percent of the payment impact from ending the transition in CY 2020 and 100 percent of the payment impact from ending the transition in CY 2021.

We believe we have provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so and many providers continue to use the ''square feet'' cost allocation methodology, which we

believe indicates that these providers believe this methodology is a sufficient method for attributing costs to this cost center. Additionally, we generally believe that increasing the amount of claims data available for use in ratesetting improves our ratesetting process. Therefore, as finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), in the CY 2021 OPPS we are using all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the APCs for CT and MRI identified in Table 1.

As noted earlier, the Deficit Reduction Act (DRA) of 2005 requires Medicare to limit Medicare payment for certain imaging services covered by the Physician Fee Schedule (PFS) to not exceed what Medicare pays for these services under the OPPS. As required by law, for certain imaging series paid for under the PFS, we cap the technical component of the PFS payment amount for the applicable year at the OPPS payment amount (71 FR 69659 through 69661). As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPPS payment amount. We will continue to monitor OPPS imaging payments in the future and consider the potential impacts of payment changes on the PFS and the ASC payment system.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2021. The Hospital OPPS page on the CMS website on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2020 claims that were used to calculate the proposed payment rates for this CY 2021 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights, on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2021, we propose to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2020 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2021 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2021 OPPS, we will continue to remove these claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2021 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we propose to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2021 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that

reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2021 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We propose to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we propose not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We refer readers to Addendum B of this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2021 payment rates for blood and blood products (which are generally identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2021, we propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(b) Payment for Blood Not Otherwise Classified (NOC) Code

Recently, providers and stakeholders in the blood products field have reported that product development for new blood products has accelerated. There may be several additional new blood products entering the market by the end of CY 2021, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products, providers and stakeholders requested that we establish a new HCPCS code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS code. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, since blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not apply in this context.

Starting January 1, 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. We assigned HCPCS code P9099 to status indicator ''E2'' (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. We took this action because HCPCS code P9099 potentially could be reported for multiple products with different costs during the same period of time. Therefore, we could not identify an individual blood product HCPCS code that would have a similar cost to HCPCS code P9099, and were not able to crosswalk a payment rate from an established blood product HCPCS code to HCPCS code P9099. Some stakeholders expressed concerns that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would receive no payment when they used unclassified blood products. Also, claim lines billed with P9099 are rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Because of the challenges of determining an appropriate payment rate for unclassified blood products, we are considering packaging the cost of unclassified blood products into their affiliated primary medical procedure. Although we typically do not package blood products under the OPPS, for unclassified blood products, we do not believe it is possible to accurately determine an appropriate rate that would apply for all of the products (potentially several, with varying costs) that may be reported using HCPCS code P9099. Packaging the cost of unclassified blood products into the payment for the primary medical service by assigning HCPCS code P9099 a status indicator of ''N'' would allow providers to report the cost of unclassified blood products to Medicare. Over time, the costs of unspecified blood products would be reflected in the payment rate for the primary medical service if the blood product remains unclassified. However, we expect that most blood products would seek and be granted more specific coding such that the unclassified HCPCS code P9099 would no longer be applicable. We believe that packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products.

Another option we considered, but ultimately rejected is similar to our policy under the OPPS to assign NOC codes to the lowest APC within the appropriate clinical family. We could crosswalk and assign the same payment rate for HCPCS code P9099 as HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), which is the lowest cost blood product with a proposed CY 2021 payment rate of $8.02 per unit. This option would provide a small, separate payment for each unclassified blood product service, and, similar to our proposal to package the costs of HCPCS code P9099 into their primary procedure, would allow for tracking of the cost utilization of unclassified blood products. However, given that the cross-walked payment rate is potentially significantly lower than the cost of the product, providers may find that packaging the cost of unclassified blood products into another medical service may generate more payment for the products over time.

Thus, for CY 2021, we propose to package the cost of unclassified blood products reported by HCPCS code P9099 into the cost of the associated primary procedure. We propose to change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''N'' (payment is packaged into other services in the OPPS). In addition, we also seek comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. If we were to adopt this option as our final policy, we would also change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''R'' (blood and blood products, paid under OPPS).

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2021, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2021 payment rates for brachytherapy sources because CY 2019 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2021 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter), we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2021 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U''.

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the final CY2020 OPPS/ASC final rule with comment period, included two claims with a geometric mean cost of HCPCS code C2645 of $1.02 per mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of 1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020.

For CY 2021, we propose to continue to assign status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter). For CY 2020, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2019 claims data available for the proposed CY 2021 rule, included one claim with over 4,000 units of HCPCS code C2645. The geometric mean cost of HCPCS code C2645 from this one claim is $1.07 per mm^2 for CY 2019. We do not believe that this one claim is adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Therefore, for CY 2021, we propose to continue assigning the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 mm^2 for CY 2021 through use of our equitable adjustment authority.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500

Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2021

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added 1 additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1'', excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2''. Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T;''
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a

comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed rule, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity

adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2021, we propose to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the complexity adjustments for ''J1'' and add-on code combinations for CY 2021, along with all of the other proposed complexity adjustments, in Addendum J to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that payment for services assigned to a New Technology APC procedures would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service starting in CY 2020 (84 FR 61167).

(3) Additional C–APCs for CY 2021

For CY 2021 and subsequent years, we propose to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any conventional

APCs to C–APCs in CY 2021. However, as discussed in section III.D.7, we propose to create an additional level for Urology and Related Services C–APCs and, as discussed in section III.D.1, we propose to create an additional level for Neurostimulator and Related Procedures C–APCs Table 3 lists the proposed C–APCs for CY 2021, all of which were established in past rules. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information.

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TABLE 3: CY 2021 C-APCs

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	*
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	*
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery

PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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c. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1—Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level—2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021. In addition, we propose to set the proposed payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic

resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2021, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2021 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2019 claims available for this CY 2021 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.b. of this CY 2021 OPPS/ASC proposed rule.

For this CY 2021 OPPS/ASC proposed rule, we were able to identify approximately 964,000 ''single session'' claims out of an estimated 4.9 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 14 percent of all eligible claims, to calculate the proposed CY 2021 geometric mean costs for the multiple imaging composite APCs. Table 4 of this CY 2021 OPPS/ASC proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2021.

Table 4 lists the HCPCS codes that we propose would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2021.

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TABLE 4: PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2021 APC 8004 (Ultrasound Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $291.56**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2021 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $220.54**
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2021 APC 8006 (CT and CTA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $425.30**
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye

70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2021 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $515.21**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech

71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2021 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $828.42**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye

72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2021, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In CY 2021, we propose no changes to this policy. We will continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the proposed changes to the packaging policies in CY 2021.

b. Packaging Policy for Non-Opioid Pain Management Treatments

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. The public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019 due to decreased utilization in the ASC setting.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies have reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling

evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only drug that meets these criteria is Exparel.

(2) Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives

Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered OPD services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Any revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B), which requires any adjustments to be made in a budget neutral manner.

As noted in the background section above, we conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug. Our updated review of claims data showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting. Decreased utilization could potentially indicate that the packaging policy is discouraging use of that treatment and that providers are choosing less expensive treatments. However, it is difficult to attribute causality of changes in utilization to Medicare packaging payment policy only. We believe that unpackaging and paying separately for Exparel addresses decreased utilization because it eliminates any potential Medicare payment disincentive for the use of this non-opioid alternative, rather than prescription opioids.

We believe we fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives in CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Therefore, for CY 2021, we propose to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

c. Clinical Diagnostic Laboratory Tests Packaging Policy

(1) Background

Prior to CY 2014, clinical diagnostic laboratory tests were excluded from payment under the hospital OPPS because they were paid separately under the Clinical Laboratory Fee Schedule (CLFS). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. Because laboratory services are paid separately under the CLFS, laboratory tests were excluded from separate payment under the OPPS. We codified this policy at 42 CFR 419.22(l).

However, in CY 2014, we revised the categories of packaged items and services under the OPPS to include certain laboratory tests. We stated that certain laboratory tests, similar to other covered outpatient services that are packaged under the OPPS, are typically integral, ancillary, supportive, dependent, or adjunctive to a primary hospital outpatient service and should be packaged under the hospital OPPS. We stated that laboratory tests and their results support clinical decision making for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations (78 FR 74939). Consequently, we finalized the policy to package payment for most laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). In the same final rule, we clarified that certain laboratory tests would be excluded from packaging. Specifically, we stated that laboratory tests would be paid separately under the CLFS when the laboratory test is the only service provided to a beneficiary or when a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service or when the laboratory test is a molecular pathology test (78 FR 74942). As explained in the CY 2014 OPPS/ASC final rule, we excluded molecular pathology tests from packaging because we believe these tests are relatively new and may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package (78 FR 74939). Based on these changes, we revised the regulation text at § 419.2(b)

and § 419.22(l) to reflect this laboratory test packaging policy.

In CY 2016, we made some modifications to this policy (80 FR 70348 through 70350). First, we clarified that all molecular pathology tests would be excluded from our packaging policy, including any new codes that also describe molecular pathology tests. In the CY 2014 OPPS/ASC final rule, we stated that only those molecular pathology codes described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 were excluded from OPPS packaging (78 FR 74939 through 74942). However, in 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes (80 FR 70348). Secondly, we excluded preventive laboratory tests from OPPS packaging and provided that they would be paid separately under the CLFS. Laboratory tests that are considered preventive are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. 100–04). As stated in the CY 2016 OPPS/ASC final rule, we make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (80 FR 70348). For consistency, we excluded from OPPS packaging those laboratory tests that are classified as preventive services. In addition, we modified our conditional packaging policy so that laboratory tests provided during the same outpatient stay (rather than specifically provided on a same date of service as the primary service) are considered as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different diagnosis and by a different practitioner than the practitioner who ordered the other hospital outpatient services. We explained in the CY 2016 OPPS/ASC final rule that this modification did not affect our policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different diagnosis than another hospital outpatient service by a practitioner different than the practitioner who ordered the other hospital outpatient service (80 FR 70349 through 70350).

In CY 2017, we modified the policy to remove the ''unrelated'' laboratory test exclusion and to expand the laboratory test packaging exclusion to apply to laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) under the CLFS. We clarified that the exception would only apply to those ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which are defined as tests that provide an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result (81 FR 79592–79594).

(2) Current Categories of Clinical Diagnostic Laboratory Tests Excluded From OPPS Packaging

Under our current policy, certain clinical diagnostic laboratory tests (CDLTs) that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. While we package most CDLTs under the OPPS, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act. Generally, when laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid under the CLFS instead of the OPPS.

(3) Proposed New Category of Laboratory Tests Excluded From OPPS Packaging

(a) Background on Protein-Based MAAAs

As part of recent rulemaking cycles, stakeholders have suggested that some protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) may have a pattern of clinical use that makes them relatively unconnected to the primary hospital outpatient service (84 FR 61439). In the CY 2018 OPPS/ASC final rule (82 FR 59299), we stated that stakeholders indicated that certain protein-based MAAAs, specifically those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as the DNA and RNA-based MAAA tests that are assigned to status indicator ''A'' under the OPPS and are paid separately under the CLFS. Notably, all of the tests described by these CPT codes (with the exception of CPT code 81490, which we discuss below) are cancer-related protein-based MAAAs. In the same final rule, stakeholders suggested that, based on the June 23, 2016 CLFS final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' in which CMS defined an ADLT under section 1834A(d)(5)(A) of the Act to include DNA, RNA, and protein-based tests, they believe that the reference to ''protein-based tests'' in the definition applies equally to the tests they identified, that is, protein-based MAAAs. Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. We note that one of the protein-based MAAAs previously requested by stakeholders to be excluded from OPPS packaging policy is CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival), which has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018. Therefore, CPT code 81538 is currently excluded from the OPPS packaging policy and paid under the CLFS instead of the OPPS when it also meets the laboratory DOS requirements.

(b) CY 2021 Proposal for Cancer-Related Protein-Based MAAAs

Since publishing the CY 2020 OPPS/ASC final rule, we have continued to consider previous stakeholder requests to exclude some protein-based MAAAs from the OPPS packaging policy. After further review of this issue, we believe that cancer-related protein-based MAAAs, in particular, may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient. Similar to molecular pathology tests, which are currently excluded from the OPPS packaging policy, cancer-related protein-based MAAAs appear to have a different pattern of clinical use, which may make them generally less tied to the primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

As we noted above, commenters to the CY 2018 OPPS/ASC final rule identified specific cancer-related protein-based MAAAs as tests that are generally not performed in the HOPD setting (82 FR 59299). In fact, those tests identified by commenters are used to guide future surgical procedures and chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which

case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we propose to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS.

The AMA CPT 2020 manual currently describes MAAAs, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' [1] The code descriptors of MAAAs include several specifics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). As the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a useful tool to identify cancer-related MAAAs that are ''protein-based''. Accordingly, using the AMA CPT 2020 manual criteria to identify a MAAA that is cancer-related, and, of those tests, identifying the ones whose analytes test proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. As discussed previously in this section, CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018 and therefore, is already paid under the CLFS instead of the OPPS when it meets the laboratory DOS requirements. As such, we propose to assign status indicator ''A'' (''Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS'') to cancer-related protein-based MAAAs as described by CPT codes 81500, 81503, 81535, 81536, and 81539. We would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

We note that commenters to the CY 2018 OPPS/ASC final rule also identified CPT code 81490 as a protein-based MAAA that should be excluded from the OPPS packaging policy and paid outside of the OPPS. However, the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we believe that payment for CPT code 81490 remains appropriately packaged under the OPPS.

We refer readers to section XVIII. of this proposed rule regarding our proposed revision to the laboratory date of service policy for cancer-related protein-based MAAAs.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61180 through 61182), we applied this policy and calculated the relative payment weights for each APC for CY 2020 that were shown in Addenda A and B to that final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2021, as we did for CY 2020, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2021 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2021, as we did for CY 2020, we propose to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2021, as we did for CY 2020, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. We note that the volume control method for clinic visit services furnished by non-excepted off-campus PBDs is subject to litigation. For a full discussion of this policy and the litigation, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY

[1] *Current Procedure Terminology* (CPT®) page 586, copyright 2020 American Medical Association. All Rights Reserved.

2021 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2020 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2021 unscaled relative payment weights.

For CY 2020, we multiplied the CY 2020 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2021, we propose to apply the same process using the estimated CY 2021 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2020 estimated aggregate weight by the unscaled CY 2021 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2021 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We propose to compare the estimated unscaled relative payment weights in CY 2021 to the estimated total relative payment weights in CY 2020 using CY 2019 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2021 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2021 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4443 to ensure that the proposed CY 2021 relative payment weights are scaled to be budget neutral. The proposed CY 2021 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of proposed rule) is included in the budget neutrality calculations for the CY 2021 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2019 forecast of the FY 2021 market basket increase, the proposed FY 2021 IPPS market basket update was 3.0 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2021.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). According to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739), the proposed MFP adjustment for FY 2021 was 0.4 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2021 OPPS is 0.4 percentage point. We also propose that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we will use such updated data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2021 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2021 an OPD fee schedule increase factor of 2.6 percent for the CY 2021 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point MFP adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV. of the proposed rule.

The adjustment described in section 1833(t)(3)(F)(ii) was required only through 2019. The requirement in section 1833(t)(3)(F)(i) of the Act that we reduce the OPD fee schedule increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II), however, applies for 2012 and subsequent years, and thus, continues to apply. In the CY 2020 OPPS/ASC final rule with comment period, we inadvertently did not amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) to reflect that the adjustment required by section 1833(t)(3)(F)(i) of the Act is the only adjustment under section 1833(t)(3)(F) that applies in CY 2020 and subsequent years. Accordingly, we propose to

amend our regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(11) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2021, we propose to increase the CY 2020 conversion factor of $80.793 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2021 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0017 for wage index changes. This adjustment was comprised of a 1.0027 proposed budget neutrality adjustment, using our standard calculation, of comparing proposed total estimated payments from our simulation model using the proposed FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9990 proposed budget neutrality adjustment for the proposed CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2021 IPPS wage index policy (85 FR 32706). We believe it is appropriate to ensure that this proposed wage index transition policy (that is, the proposed CY 2021 5 percent cap on wage index decreases) does not increase estimated aggregate payments under the OPPS beyond the payments that would be made without this transition policy. We propose to calculate this budget neutrality adjustment by comparing total estimated OPPS payments using the FY 2021 IPPS wage index, adopted on a calendar year basis for the OPPS, where a 5 percent cap on wage index decreases is not applied to total estimated OPPS payments where the 5 percent cap on wage index decreases is applied. These two proposed wage index budget neutrality adjustments would maintain budget neutrality for the proposed CY 2021 OPPS wage index (which, as we discuss in section II.C of the proposed rule, would use the FY 2021 IPPS post-reclassified wage index and any adjustments, including without limitation any adjustments finalized under the IPPS related to the proposed adoption of the revised OMB delineations).

For the CY 2021 OPPS, we are maintaining the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We propose to calculate a CY 2021 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2021 payments under section 1833(t) of the Act, including the proposed CY 2021 cancer hospital payment adjustment, to estimated CY 2021 total payments using the CY 2020 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2021 estimated payments applying the proposed CY 2021 cancer hospital payment adjustment were the same as estimated payments applying the CY 2020 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For this CY 2021 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2021 would equal approximately $783.2 million, which represented 0.93 percent of total projected CY 2021 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.88 percent estimate of pass-through spending for CY 2020 and the 0.93 percent estimate of proposed pass-through spending for CY 2021, resulting in a proposed decrease to the conversion factor for CY 2021 of 0.05 percent.

We also estimate a 0.85 percent upward adjustment to nondrug OPPS payment rates as a result of our payment proposal for separately payable nonpass-through drugs purchased under the 340B Program. Applying the proposed payment policy for drugs purchased under the 340B Program, as described in section V.B.6. of this proposed rule, results in an estimated reduction of approximately $427 million in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after applying this proposed payment methodology for drugs purchased under the 340B Program, we propose to apply an offset of approximately $427 million to the OPPS conversion factor, which would result in an adjustment of 1.0085 to the OPPS conversion factor.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2021. We estimate for the proposed rule that outlier payments would be 1.01 percent of total OPPS payments in CY 2020; the 1.00 percent for proposed outlier payments in CY 2021 would constitute a 0.01 percent decrease in payment in CY 2021 relative to CY 2020.

For this CY 2021 OPPS/ASC proposed rule, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2021 of $82.065 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of –1.632 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2021, we propose to amend § 419.32 by adding a new paragraph (b)(1)(iv)(B)(*11*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2020, CY 2021, and subsequent years to satisfy the statutory requirements of section 1833(t)(3)(F) of the Act. We propose to use a reduced conversion factor of $82.065 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of –1.632 in the conversion factor relative to hospitals that met the requirements).

For CY 2021, we propose to use a conversion factor of $83.697 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2021, the required proposed wage index budget neutrality adjustment of approximately 1.0017, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.05 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a

proposed conversion factor for CY 2021 of $83.697.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2021 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the internet on the CMS website), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2021 pre-reclassified wage index that we would use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2021, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2020 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; and for FY 2020, 84 FR 42312.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2021 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of all proposed changes to the FY 2021 IPPS wage indexes.

Furthermore, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to the statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014

and July 1, 2015. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01, effective January 1, 2019, beginning with the CY 2019 wage index.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, as we stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32696 through 32697), the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some material modifications that have a number of downstream effects, such as IPPS hospital reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf.* According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data.''

As noted previously, while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs would be split apart. In addition, we stated in the FY 2021 IPPS/LTCH PPS proposed rule that the revised OMB delineations would affect various hospital reclassifications, the outmigration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule for a complete discussion of the revised OMB delineations we propose to adopt under the IPPS and the effects of these revisions on the FY 2021 IPPS wage indexes (85 FR 32696 through 32707, 32717 through 32728). We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. In addition, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to apply a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020 as a proposed transition wage index to help mitigate any significant negative impacts of adopting the revised OMB delineations (85 FR 32706 through 32707).

As further discussed below, in this CY 2021 OPPS proposed rule, we propose to adopt these updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indexes. Similar to our discussion in the FY 2021 IPPS/LTCH PPS proposed rule, we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the OPPS wage index system by creating a more accurate representation of geographic variations in wage levels.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2021, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2021. Therefore, any adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, any adjustments that we may finalize related to the proposed adoption of the revised OMB delineations (such as a cap on wage index decreases and revisions to hospital reclassifications), would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. (We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) and the proposed FY 2021 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2021 OPPS wage index, we refer readers to section II.B. of this CY 2021 OPPS/ASC proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In this CY 2021 OPPS/ASC proposed rule, we propose to continue this policy for CY 2021, and are including a brief summary of the major proposed FY

2021 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2021, which we have summarized below. We refer readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of the proposed changes to the FY 2021 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For CY 2021, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, the wage index that would apply for CY 2021 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities (84 FR 42325 through 42336). In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed earlier in this proposed rule.

For CMHCs, for CY 2021, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. We also propose that the wage index that would apply to CMHCs would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed earlier in this proposed rule. In addition, we propose that the wage index that would apply to CMHCs for CY 2021 would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4 associated with the FY 2021 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2021 IPPS/LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2021. We are including the outmigration adjustment information from Table 2 associated with the FY 2021 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this CY 2021 OPPS/ASC proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the proposed FY 2021 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2021 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We propose to update the default ratios for CY 2021 using the most recent cost report data. We will update these ratios in the final rule with comment period if more recent cost report data are available.

We are no longer publishing a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the downloads section of the web page.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2021

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for

rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2019. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For CY 2021, we propose to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2021

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR was 0.90. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266). For CY 2019, the target PCR was 0.88, as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58871 through 58873). For CY 2020, the target PCR was 0.89, as discussed in the CY 2020 OPPS/ASC final rule with comment period (83 FR 61190 through 61192).

2. Proposed Policy for CY 2021

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act.

We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2021. To calculate the proposed CY 2021 target PCR, we are using the same extract of cost report data from HCRIS, as discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule and proposed rule, used to estimate costs for the CY 2021 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the proposed CY 2021 APC relative payment weights (3,527 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,464 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, we propose that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

Table 5 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2021, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2021 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2021 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 5: ESTIMATED CY 2021 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2021 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	32.8%
050660	USC Norris Cancer Hospital	11.2%
100079	Sylvester Comprehensive Cancer Center	12.8%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.5%
220162	Dana-Farber Cancer Institute	35.8%
330154	Memorial Sloan-Kettering Cancer Center	39.4%
330354	Roswell Park Cancer Institute	13.6%
360242	James Cancer Hospital & Solove Research Institute	12.7%
390196	Fox Chase Cancer Center	10.4%
450076	M.D. Anderson Cancer Center	41.9%
500138	Seattle Cancer Care Alliance	44.8%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2020, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,075 (the fixed-dollar amount threshold) (84 FR 61192 through 61194). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2019 OPPS payments, using CY 2019 claims available for this CY 2021 OPPS/ASC proposed rule is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2019, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this CY 2021 OPPS/ASC proposed rule, we estimate that we paid approximately 1.01 percent of the total aggregated OPPS payments in outliers for CY 2019.

For this CY 2021 OPPS/ASC proposed rule, using CY 2019 claims data and CY 2020 payment rates, we estimated that the aggregate outlier payments for CY 2020 would be approximately 1.01 percent of the total CY 2020 OPPS payments. We provided estimated CY 2021 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation for CY 2021

For CY 2021, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the

proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of this CY 2021 OPPS/ASC proposed rule, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this CY 2021 OPPS/ASC proposed rule and proposed rule.

To ensure that the estimated CY 2021 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $5,300.

We calculated the proposed fixed-dollar threshold of $5,300 using the standard methodology most recently used for CY 2020 (84 FR 61192 through 61194). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2019 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2021 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.131096 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32098). We used an inflation factor of 1.06353 to estimate CY 2020 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR inflation adjustment factor that we propose to apply for the FY 2021 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2021 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2021, we propose to apply an adjustment factor of 0.975271 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2021. The methodology for calculating the proposed adjustment is discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32098).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2020 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.976271 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.131096 to approximate CY 2021 charges). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $5,300, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, as we proposed, we are continuing the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2021 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the internet on the CMS website) was calculated by multiplying the proposed CY 2021 scaled weight for the APC by the CY 2021 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services

provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to the proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We noted that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to the proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2021 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 *$ (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, for the CY 2021 OPPS wage index, we propose to adopt the updated OMB delineations based on OMB Bulletin No. 18–04 and any related IPPS wage index adjustments that may be finalized in the FY 2021 IPPS/LTCH PPS final rule, as discussed in section II.C. of this proposed rule. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2021 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We also propose to continue to apply for the CY 2021 OPPS wage index any other adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we propose to apply for the CY 2021 OPPS, we refer readers to section II.C. of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2021 IPPS, which are listed in Table 2 associated with the FY 2021 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2021 IPPS Proposed Rule Home Page'' and select ''FY 2021 Proposed Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

$X_a = .60 *$ (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 *$ (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2021 full national unadjusted payment rate for APC 5071 is $634.92. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $622.54. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The proposed FY 2021 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2021 wage index policies, is 1.3376. The labor-related portion of the proposed full national unadjusted payment is approximately $509.56 (.60 * $634.92 * 1.3376). The labor-related portion of the proposed reduced national unadjusted payment is approximately $499.62 (.60 * $622.54 * 1.3376). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $253.97 (.40 * $634.92). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $249.02 (.40 * $622.54). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $763.53 ($509.56 + $253.97). The sum of the portions of the proposed reduced national adjusted payment is approximately $748.64 ($499.62 + $249.02).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2021, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2021 are included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2021, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a

decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

• If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $126.99 is approximately 20 percent of the full national unadjusted payment rate of $634.92. For APCs with only a minimum unadjusted copayment in Addenda A and B to proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The proposed unadjusted copayments for services payable under the OPPS that will be effective January 1, 2021, are shown in Addenda A and B to proposed rule (which are available via the internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2021 OPD fee schedule increase factor discussed in section II.B. of proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

• Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

• Category III CPT codes, which describe new and emerging technologies, services, and procedures; and

• Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) while the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim

assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes and finalize our proposals through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. of this proposed rule (Proposed CY 2021 OPPS Payment Status and Comment Indicators), we discuss the various status indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this CY 2021 OPPS/ASC proposed rule.

1. April 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2020 update, 13 new HCPCS codes were established and made effective on April 1, 2020. These codes and their long descriptors are listed in Table 6. Through the April 2020 OPPS quarterly update CR (Transmittal 10013, Change Request 11691, dated March 25, 2020), we recognized several new HCPCS codes for separate payment under the OPPS. In this CY 2021 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed Table 6. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective April 1, 2020 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

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TABLE 6: NEW HCPCS CODES EFFECTIVE APRIL 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C9053*	Injection, crizanlizumab-tmca, 1 mg	CH	G	9342
C9056**	Injection, givosiran, 0.5 mg	CH	G	9343
C9057#	Injection, cetirizine hydrochloride, 1 mg	CH	G	9344
C9058##	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	CH	G	9345
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	NP	E1	N/A
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	NP	Q4	N/A
0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy	NP	Q4	N/A
0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	NP	Q4	N/A
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	NP	Q4	N/A
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	NP	Q4	N/A
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	NP	A	N/A
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	NP	A	N/A

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

2. July 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2020 update, over 100 new codes were established and made effective July 1, 2020. The codes and long descriptors are listed in Table 7. Through the July 2020 OPPS quarterly update CR (Transmittal10207, Change Request 11814, dated July 2, 2020), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2021 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2020, all of which are listed in Table 7. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective July 1, 2020 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	NP	H	2029
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N	N/A
C9059	Injection, meloxicam, 1 mg	NP	G	9371
C9061	Injection, teprotumumab-trbw, 10 mg	NP	G	9355
C9063	Injection, eptinezumab-jjmr, 1 mg	NP	G	9357
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	NP	G	9346
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	NP	N	N/A
C9760	Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	NP	T	1589
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	NP	Q3	5524
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	NP	Q3	5524
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	NP	J1	5192
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	NP	J1	5193

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J1	5193
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J1	5194
G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NP	J1	5193
G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NP	J1	5194
J0223	Injection, givosiran, 0.5 mg	NP	G	9343
J0591	Injection, deoxycholic acid, 1 mg	NP	E1	N/A
J0691	Injection, lefamulin, 1 mg	NP	G	9332
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	NP	G	9362
J0791	Injection, crizanlizumab-tmca, 5 mg	NP	G	9359
J0896	Injection, luspatercept-aamt, 0.25 mg	NP	G	9347
J1201	Injection, Cetirizine hydrochloride, 0.5 mg	NP	G	9361
J1429	Injection, golodirsen, 10 mg	NP	G	9356
J1558	Injection, immune globulin (Xembify), 100 mg	NP	K	9372
J3399	Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5x1015 vector genomes	NP	K	9373
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	NP	G	9198

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	NP	G	9354
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dos	NP	N	N/A
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	NP	G	9364
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	NP	N	N/A
J9246	Injection, melphalan (evomela), 1 mg	NP	K	9375
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	NP	G	9353
Q4227#	Amniocore, per square centimeter	NP	N	N/A
Q4228#	BioNextPATCH, per square centimeter	NP	N	N/A
Q4229#	Cogenex amniotic membrane, per square centimeter	NP	N	N/A
Q4230#	Cogenex flowable amnion, per 0.5 cc	NP	N	N/A
Q4231#	Corplex P, per cc.	NP	N	N/A
Q4232#	Corplex, per square centimeter	NP	N	N/A
Q4233#	Surfactor or Nudyn, per 0.5 cc	NP	N	N/A
Q4234#	Xcellerate, per square centimeter	NP	N	N/A
Q4235#	Amniorepair or altiply, per square centimeter	NP	N	N/A
Q4236#	CarePATCH, per square centimeter	NP	N	N/A
Q4237#	Cryo-cord, per square centimeter	NP	N	N/A
Q4238#	Derm-maxx, per square centimeter	NP	N	N/A
Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	NP	N	N/A
Q4240#	Corecyte, for topical use only, per 0.5 cc	NP	N	N/A
Q4241#	Polycyte, for topical use only, per 0.5 cc	NP	N	N/A
Q4242#	Amniocyte plus, per 0.5 cc	NP	N	N/A
Q4244#	Procenta, per 200 mg	NP	N	N/A
Q4245#	Amniotext, per cc	NP	N	N/A
Q4246#	Coretext or Protext, per cc	NP	N	N/A
Q4247#	Amniotext patch, per square centimeter	NP	N	N/A
Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	NP	N	N/A
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	G	9367
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	NP	G	9345
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	NP	E2	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NP	J1	5114
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	NP	T	5372
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	NP	T	5372
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	NP	T	5722
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	NP	N	N/A
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	NP	J1	5361
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	NP	J1	5361
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	NP	Q4	N/A
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	NP	Q4	N/A
0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	NP	V	5012
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center	NP	Q1	5741

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
	technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days			
0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	NP	M	N/A
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	NP	V	5012
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	NP	S	5741
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	NP	E1	N/A
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	NP	E1	N/A
0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	NP	E1	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	NP	E1	N/A
0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	NP	E1	N/A
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	NP	J1	5231
0615T	Eye-movement analysis without spatial calibration, with interpretation and report	NP	Q1	5734
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	NP	J1	5491
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	NP	J1	5492
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	NP	J1	5492
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	NP	J1	5375
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	NP	A	N/A
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	NP	A	N/A
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	NP	Q4	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	NP	A	N/A
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	NP	Q4	N/A
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	NP	A	N/A
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	NP	Q4	N/A
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)	NP	A	N/A
0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	NP	A	N/A
0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	NP	A	N/A
0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	NP	A	N/A
0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	NP	A	N/A
0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	NP	A	N/A
0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	NP	A	N/A
0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	NP	A	N/A
0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	NP	A	N/A
0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	NP	A	N/A
0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	NP	A	N/A
0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	NP	A	N/A
0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	NP	A	N/A
0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	NP	A	N/A
0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	NP	A	N/A
0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	NP	A	N/A
0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	NP	A	N/A
0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	NP	A	N/A
0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	NP	A	N/A

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	NP	A	N/A
0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	NP	A	N/A
0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	NP	A	N/A

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR Part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271.

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3. October 2020 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2020 in the CY 2021 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2022 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2020 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2021, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to those new HCPCS codes that are effective October 1, 2020 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2021 in the CY 2021 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2022 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the HCPCS C-codes and G codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2021 OPPS/ASC final rule with comment period, January 2021 OPPS Update CR, and the CMS HCPCS website.

For CY 2021, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the

current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2021 OPPS update, we received the CPT codes that will be effective January 1, 2021 from AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2021 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers will be included in the CY 2021 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2021 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2021. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

Finally, in Table 8, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

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TABLE 8: COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

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B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the service.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2021, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of

representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2021 OPPS update will be discussed in the relevant specific sections throughout the CY 2021 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2021, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2021 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we propose changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2021 OPPS/ASC proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2021 included in this proposed rule are related to changes in costs of services that were observed in the CY 2019 claims data newly available for CY 2021 ratesetting. Addendum B to this CY 2021 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2020 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2021, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2019 claims data available for this CY 2021 proposed rule, we found 18 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2021, and found that all of the 18 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for this proposed rule. We note that we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 of this proposed rule lists the 18 APCs for which we propose to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before December 31, 2019. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2019, and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

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TABLE 9: PROPOSED CY 2021 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2021 APC	Proposed CY 2021 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5112	Level 2 Musculoskeletal Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2020, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase adjusted for multifactor productivity. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial

projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. (We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.)

We note that, in a budget neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2021, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a new technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believe it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believe that it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we define as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume service. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believe using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believe having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that

we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we will use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identify the most appropriate payment rate for a service, we will assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2021, we propose to continue the policy we adopted in CY 2019 under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. Additional details on our policy is available in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893).

3. Procedures Assigned to New Technology APC Groups for CY 2021

As we described in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2021, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we propose to continue to assign to standard APCs, and one that we propose to continue to assign to a New Technology APC for CY 2021. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

For the procedure described by CPT code 0398T, we have identified 149 paid claims for CY 2019 with a geometric mean of $12,798.38. The number of claims for the service means that the procedure is no longer a low-volume new technology service, and we will use the geometric mean of the CY 2019 claims data to determine the cost of the service for its APC assignment. We reviewed the OPPS to determine whether CPT code 0398T could be assigned to a clinical APC. The most appropriate clinical APC family for the service would be the Neurostimulator and Related Procedures APC series (APC 5461–5464). However, there is large payment rate difference between Level 2 Neurostimulator and Related Procedures (APC 5462) with a payment rate of $6,169.27 and Level 3 Neurostimulator and Related Procedures (APC 5463) with a payment rate of $19,737.37. Based on the geometric mean cost of CPT code 0398T available for this proposed rule, we believe the payment rate for APC 5462 would be too low for CPT code 0398T since it is more than $6,000 less than the geometric mean cost for CPT code 0398T, and we believe the payment rate for APC 5463 would be too high since it is around $6,800 more than the geometric mean cost for CPT code 0398T.

In addition, given the significant difference in the payment rate between APC 5462 and 5463, we believe a restructuring of this APC family would be appropriate. We believe creating an additional payment level between the two existing APC levels would allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Please refer to section III.D.1 for detailed explanation of our proposal to reorganize the Neurostimulator and Related Procedures APCs (APCs 5461–5464). Reorganizing the Neurostimulator and Related Procedures APCs would create a proposed Level 3 APC to be referred to as ''Proposed APC 5463'' with a payment rate of approximately $12,286 that is close to the geometric mean of CPT code 0398T which is approximately $12,798. The payment rate of proposed APC 5463 is representative of the cost of the service described by CPT code 0398T. Therefore, we propose to reassign the service described by CPT code 0398T to the proposed new Level 3 APC for Neurostimulator and Related Procedures (Proposed APC 5463) for CY 2021. The current and proposed APC assignments, status indicators, and payment rates for CPT code 0398T are found in Table 10. We refer readers to Addendum B of the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 10: CY 2021 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURE

CPT/ HCPCS Code	Long Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC	CY 2020 OPPS Payment Rate	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Proposed CY 2021 OPPS Payment Rate
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1575	$12,500.50	J1	5463	Refer to OPPS Addendum B.

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the Food and Drug Administration (FDA) in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 OPPS/ASC final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data for 6 claims used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017, but closer to the CY 2016 payment rate for the procedure. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50

in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large fluctuations in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2018, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

For CY 2019, the reported cost of the Argus® II procedure based on the geometric mean cost of 12 claims from the CY 2017 hospital outpatient claims data was approximately $171,865, which was approximately $49,364 more than the payment rate for the procedure for CY 2018. In the CY 2019 OPPS/ASC final rule with comment period, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS (83 FR 58897 through 58898). In addition, the number of claims submitted continued to be very low for the Argus® II procedure. We stated that we continued to believe that it is important to mitigate significant payment fluctuations for a procedure, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

As discussed in section III.C.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893), we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more representative of the likely cost of the service. We stated that we believed the likely cost of the Argus® II procedure is higher than the geometric mean cost calculated from the claims data used for the CY 2018 OPPS/ASC final rule with comment period but lower than the geometric mean cost calculated from the claims data used for the CY 2019 OPPS/ASC final rule with comment period.

For CY 2019, we analyzed claims data for the Argus® II procedure using 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year that the Argus® II received transitional device pass-through payments (CY 2015) and the first 2 years since device pass-through payment status for the Argus® II expired. We found that the geometric mean cost for the procedure was approximately $145,808, the arithmetic mean cost was approximately $151,367, and the median cost was approximately $151,266. As we do each year, we reviewed claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). For CY 2019, the estimated costs using all three potential statistical methods for determining APC assignment under the New Technology low-volume payment policy fell within the cost band of New Technology APC 1908, which is between $145,001 and $160,000. Therefore, we reassigned the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2019.

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continues to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continues to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2021, we propose to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC.

For CY 2021, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,807, the arithmetic mean cost to be approximately $154,504, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC

1908, with the estimated cost being between $145,001 and $160,000.

Accordingly, we propose to maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001-$160,000)), with a proposed payment rate of $152,500.50 for CY 2021. We note that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

c. Administration of Subretinal Therapies Requiring Vitrectomy

CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by the FDA in December of 2017, and is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[2] This therapy is administered through a subretinal injection, which stakeholders describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.'' [1]

Stakeholders, including the manufacturer of Luxturna®, recommend HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[3] However, the manufacturer contends the administration is not currently described by any existing codes as HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. For J3398, a typical patient would receive a standard dose of 150 billion vector genomes, with an approximate payment rate of $436,575 (we refer readers to Addendum B of this proposed rule for the proposed payment rate associated with J3398).

It is important to note that CPT code J3398 was granted drug pass-through status under the OPPS as of July 1, 2018 and is assigned to status indicator ''G''. (We refer readers to Addendum D of this proposed rule for the list of proposed status indicator definitions for CY2021). J3398 is scheduled to have its drug pass-through status expire June 30, 2021, at which point J3398 would be packaged into the payment for any primary service with which it is billed when that primary service is assigned to a comprehensive APC (C–APC). A C–APC packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure (For a full discussion and background on C–APCs, see section II.A.2.b). Based on information from the manufacturer of Luxturna, we believe that CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) would commonly be billed with the service described by HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach), which describes the administration of the gene therapy, and which is assigned to a comprehensive APC, (APC 5492—Level 2 Intraocular Procedures). Thus, when its pass-through status expires, payment for CPT code J3398, the primary therapy, would be inappropriately packaged into payment for HCPCS code 67036, its administration procedure.

CMS recognizes the necessity to accurately describe the unique administration procedure that is required to administer the therapy described by CPT J3398. We propose to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We believe that this new HCPCS code accurately describes the service associated with intraocular administration of HCPCS code J3398. CMS recognizes that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C97X1. CMS also recognizes that it is not prudent for the code that describes the administration of this gene therapy, C97X1, to be assigned to the same C–APC that is assigned to HCPCS code 67036, as this would inappropriately package the primary therapy, J3398, into the code that represents the process to administer the gene therapy.

For CY 2021, we propose to assign the services described by C97X1 to a new technology payment band based on the geometric mean cost for HCPCS code 67036. For CY 2021, HCPCS code 67036 has a geometric mean cost of $3407.84. Therefore, for CY 2021 we propose to assign C97X1 to APC 1561—New Technology—Level 24 ($3001–$3500). Please see Table 11 for proposed descriptors and APC assignment.

TABLE 11: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C97X1 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 Placeholder HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C97X1	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561

[2] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[3] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf.*

d. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for this proposed rule, there were 4 claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we propose for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $4,051, the arithmetic mean cost to be approximately $4,067, and the median cost to be approximately $4,067. All three potential statistical methodologies used to estimate the cost of the service procedure fall within the cost band for New Technology APC 1563, with the estimated cost being between $4,001 and $4,500. Accordingly, we propose to change the assignment of the HCPCS code C9751 to APC 1563 (New Technology—Level 26 ($4001–$4500)), with a proposed payment rate of $4,250.50 for CY 2021. Details regarding HCPCS code C9751 are shown in Table 12.

TABLE 12: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1563

e. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single frequency claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and the number of single frequency claims was only two claims above the threshold for the new technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to

calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our new technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for Heartflow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12 and that the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T that are available for this proposed rule. Specifically, using the most recently available data for this proposed rule (that is, CY 2019), we identified 2,820 claims billed with CPT code 0503T including 415 single frequency claims. These totals are well above the threshold of 100 claims for a procedure to be evaluated using the new technology APC low-volume policy. Therefore, we propose to use our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T.

Our analysis found the geometric mean cost for CPT code 0503T is approximately $851. Therefore, we propose to reassign the service described by CPT code 0503T in order to adjust the payment rate to better reflect the cost for the service. While we considered proposing to reassign CPT code 0503T to APC 5724 (Level 4—Diagnostic Tests and Related Services), which has a payment rate of around $903 based on the clinical and resource similarity to other services within that APC, we did not propose such reassignment because the payment rate for the new technology APC is closer to the geometric mean costs of CPT code 0503T. Nonetheless, we welcome comments on whether reassignment to the clinical APC would be more appropriate. Therefore, we propose to reassign the service described by CPT code 0503T to New Technology APC 1510 (New Technology—Level 10 ($801–$900)), with a proposed payment rate of $850.50 for CY 2021.

f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. Table 13 reports code descriptors, status indicators, and APC assignments for these CPT codes. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $ 2,750.50.

We have not received any claims that have been billed with CPT codes 78431, 78432, or 78433. Therefore, we propose to continue to assign these CPT codes to the same new technology APCs as they were in CY 2020. The proposed CY 2021 payment rate for the codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

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TABLE 13: CY 2021 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Proposed CY 2021 OPPS SI	Proposed OPPS CY 2021 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1523
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

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g. Pathogen Test for Platelets/Rapid Bacterial Testing

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment was announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology-Level 1C ($21-$30)) with a status indicator ''S'' and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator ''S''. For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology—Level 1D ($31-$40) based on the latest claims data

used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 update, we believe that we have sufficient claims data to reassign the code from a New Technology APC to a clinical APC and note that HCPCS code P9100 has been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believe that we should reassign the code to a clinical APC. Specifically, our claims data for this proposed rule shows a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims). Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believe that HCPCS code P9100 should be reassigned to clinical APC 5732 whose geometric mean cost is approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted between January 1, 2019, and December 30, 2019, our analysis of the latest claims data for this proposed rule supports reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource homogeneity to the procedures and services in the APC. Therefore, we propose to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The proposed CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

h. V-Wave Interatrial Shunt Procedure (HCPCS Code C9758; APC 1589)

A randomized, double-blinded control IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

No claims have been reported for HCPCS code C9758. Therefore, we propose to continue to assign the service to New Technology APC 1589 for CY 2021. Details about the HCPCS code and its APC assignment are shown in Table 14. The proposed CY 2021 payment rate for V-Wave interatrial shunt procedure can be found in Addendum B to proposed rule (which is available via the internet on the CMS website).

TABLE 14: CY 2021 OPPS APC AND STATUS INDICATOR FOR V-WAVE INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1589

i. Supervised Visits for Esketamine Self-Administration (HCPCS Codes G2082 and G2083 APCs 1508 and 1511)

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration and includes 2 hours post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082, but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50.

No Medicare OPPS claims have been reported for either HCPCS code G2082 or G2083. Therefore, we propose to continue to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. Details about the HCPCS codes and their APC assignments are shown in Table G15 below. The proposed CY 2021 payment rate for esketamine self-administration can be found in Addendum B to proposed rule (which is available via the internet on the CMS website).

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TABLE 15: CY 2021 OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Proposed CY 2021 OPPS SI	Proposed OPPS CY 2021 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1511

D. Proposed OPPS APC-Specific Policies

1. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule, we also made the Level 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS final rule, we also established the Level 1 Neurostimulator and Related Procedure APC (APC 5461) as a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for CY 2021 OPPS proposed rule, we believe that it is appropriate to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs. Creating this APC allows for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we propose to establish a five-level APC structure for the Neurostimulator and Related Procedures series. We note that in addition to creating this new level, we also propose to assign CPT 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to this new Level 3 APC, as discussed in further detail in section III.C.3.A of this proposed rule with comment period.

Table 16 displays the proposed CY 2021 Neurostimulator and Related Procedures APC series' structure and APC geometric mean costs

TABLE 16: PROPOSED NEUROSTIMULATOR AND RELATED PROCEDURES APCS FOR CY 2021

APC	APC Descriptor	SI	CY 2020 OPPS Final Geometric Mean Cost	CY 2021 Proposed Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,080.60	$3,370.70
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,053.71	$6,105.05
5463	Level 3 Neurostimulator and Related Procedures	J1	$18,863.68	$12,286.43
5464	Level 4 Neurostimulator and Related Procedures	J1	$28,490.84	$20,032.49
5465	Level 5 Neurostimulator and Related Procedures	J1	N/A	$28,876.14

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2. IDx-DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5732)

As stated in a press release issued by the FDA on April 11, 2018, the IDx-DR is the ''first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes'' (*https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye*). Approved for marketing by the FDA in April 2018, the artificial intelligence algorithm provides a clinical decision without the need for a clinician to also interpret the image. A provider uploads the digital images of the patient's retinas to a cloud server on which the IDx-DR software is installed, and once analysis is completed, the provider is given one of the following two results:

- More than mild diabetic retinopathy detected: Refer to an eye care professional; or
- negative for more than mild diabetic retinopathy; rescreen in 12 months.

The test itself generally takes about 5 minutes to complete and does not need to be performed by a clinician. The test associated with the IDx-DR technology will receive a new CPT code effective January 1, 2021, and with the establishment of the new code, the CPT Editorial Panel is also revising the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx-DR test.

Based on our evaluation of the service, we believe that IDx-DR is a diagnostic test that should be payable under the hospital OPPS, similar to existing CPT codes 92227 and 92228, which are assigned to APC 5732 (Level 2 Minor Procedures) and status indicator ''Q1.'' Based on its clinical similarity to CPT codes 92227 (Remote imaging for detection of retinal disease (for example, retinopathy in a patient with diabetes) with analysis and report under physician supervision, unilateral or bilateral) and 92228 (Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral), we believe that the IDx-DR test should also be assigned to APC 5732 (Level 2 Minor Procedures) and status indicator ''Q1.'' Consequently, we propose to assign the new IDx-DR CPT code to APC 5732 with a proposed payment rate of $33.16 for CY 2021. We note that we propose to assign the code to status indicator ''Q1'' to indicate that the code is conditionally packaged when performed with another service on the same day. Because the IDx-DR test will most often be performed as part of a visit, we believe that packaging the cost into the primary service is appropriate. We note that under the OPPS, the current E&M visit code (G0463) is paid separately when not billed with a C–APC, and we believe this payment includes the cost of providing the IDx-DR test. Generally, our process for tests with minimal costs is to package the cost into the primary service. Because the IDx-DR test will generally be part of another service provided on the same day, and involve minimal cost, we believe that conditionally packaging the payment for the 5-minute IDx-DR test is appropriate for this test in the hospital outpatient setting.

In summary, we propose to assign the new CPT code associated with IDx-DR to APC 5732 and status indicator ''Q1''. Table 17 lists the proposed APC and SI for placeholder CPT code 9225X, which is associated with the IDx-DR test. The final CPT code number for placeholder code 9225X will be included in the CY 2021 OPPS/ASC final rule with comment period. The proposed CY 2021 payment rate for CPT code 9225X can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website. Furthermore, for discussion on the proposed PFS payment for placeholder CPT code 9225X, refer to the CY 2021 PFS Proposed Rule.

TABLE 17: PROPOSED CY 2021 APC AND SI ASSIGNMENTS FOR CPT CODES 92227, 92228, AND 9225X

CY 2020 CPT Code	Place-holder CPT Code	CY 2021 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
N/A	9225X	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	NP	Q1	5732
92227	N/A	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	N/A	Q1	5732
92228	N/A	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	N/A	Q1	5732

3. Intraocular Procedures (APCs 5491 Through 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) was assigned to the APC 5495 (Level 5 Intraocular Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median cost under our payment policy for low-volume device-intensive procedures because the APC contained a low volume of claims. The low volume device-intensive procedures payment policy is discussed in more detail in section III.C.2. of the proposed rule.

In the CY 2019 OPPS, we assigned procedure code CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) (83 FR 58917 through 58918). We made this change based on the similarity of the estimated cost for the single claim of $12,939.75 to that of the APC ($11,427.14). However, this created a discrepancy in payments between the OPPS setting and the ASC setting in which the ASC payments would be significantly lower than the OPPS payments for the same service because of the difference in estimated cost for the encounter determined under a comprehensive methodology within the OPPS and the estimated cost determined under the payment methodology for device intensive services within the ASC payment system.

In CY 2020 OPPS rulemaking, we reestablished APC 5495 (Level 5 Intraocular Procedures) because we believed that the procedure described by CPT code 0308T would be most appropriately placed in the APC based on its estimated cost (84 FR 61249 through 61250). Assignment of the procedure to the Level 5 Intraocular Procedures APC was consistent with its historical placement and would also address the large discrepancy in payment for the procedure between the OPPS and the ASC payment system. We note that we also implemented a policy where the payment for a service when performed in an ASC (84 FR 61399 through 61400), would be no higher than the OPPS payment rate for the service when performed in the hospital outpatient setting.

In reviewing the claims data available for CY 2021 ratesetting, there was a single claim containing the code 0308T that was unable to be used for the ratesetting process. In addition, this code and its APC have historically had relatively low claims volume for ratesetting purposes. While there are no claims usable for ratesetting in the CY 2021 OPPS proposed data under our standard process, we still need to determine a payment weight for the APC. We believe that the most recently available data that we used to set payment for this service in the CY 2020 OPPS final rule is an appropriate proxy for both the procedure's estimated cost and its relative payment weight. We note that this proposed policy to use prior year claims data in ratesetting is similar to the application of a geometric mean cost floor to the Partial Hospitalization APCs, as initially established in the CY 2020 OPPS/ASC final rule (84 FR 61339 through 61347). Therefore, we believe it is appropriate to propose to use the median cost of $20,229.78 for CPT 0308T, calculated from claims data used in the CY 2020 OPPS final rule, to establish the payment weight for the CY 2021 OPPS for CPT code 0308T. We will continue to monitor the claims available for ratesetting as they are available for the CY 2021 OPPS final rule.

To summarize, for CY 2021, we propose to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore propose to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Under this proposal, the proposed CY 2021 OPPS payment rate for the service would be established based on the median cost, as discussed in section V.A.5. of the proposed rule, because it is a device intensive procedure assigned to an APC with fewer than 100 total annual claims within the APC. Therefore, the proposed APC assignment for CPT 0308T would be based on the CY 2019 OPPS final rule median cost of $20,229.78.

4. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure

for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for this CY 2021 OPPS/ASC proposed rule, we continue to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate. Therefore, we propose to maintain the APC structure for the CY 2021 OPPS update.

In the CY 2020 OPPS/ASC final rule, we discussed issues related to the APC assignment of CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level) to APC 5115 (84 FR 61253 through 61254). Specifically, commenters believed that the code was inappropriately assigned to APC 5115 due to one hospital inaccurately reporting its costs and charges. While we recognized the concerns that the commenters described, we noted that it is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. For the CY 2021 OPPS, the geometric mean cost of CPT code 22869 has increased slightly relative to the prior year, from $11,023.45 to $12,788.56. However, the geometric mean costs of the Level 5 and Level 6 Musculoskeletal Procedures APCs are $12,102.02 and $15,975.08, respectively, and so, based on the data that is available, we continue to believe that it is appropriate to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures APC).

For the CY 2021 OPPS, we also propose to remove codes that were previously on the Inpatient Only List and assign them to clinical APCs. Many of these codes are being proposed for APC assignment to the Musculoskeletal Procedures APC series, and so there may be effects on the geometric means as the limited claims data for those codes is included in OPPS ratesetting. For a more detailed discussion of the proposal to remove certain codes from the inpatient only list, please see section IX.B. of this proposed rule,

Table 18 displays the proposed CY 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 18: PROPOSED MUSCULOSKELETAL PROCEDURES APCS FOR CY 2021

APC	Group Title	HCPCS Codes Assigned to APC in this CY 2021 OPPS/ASC Proposed Rule	CY 2020 Final APC Geometric Mean Cost	CY 2021 Proposed APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	$210.99	$206.66
5112	Level 2 Musculoskeletal Procedures	136	$1,326.17	$1,367.39
5113	Level 3 Musculoskeletal Procedures	411	$2,678.42	$2,777.09
5114	Level 4 Musculoskeletal Procedures	445	$5,852.95	$6,136.58
5115	Level 5 Musculoskeletal Procedures	120	$11,644.09	$12,101.07
5116	Level 6 Musculoskeletal Procedures	50	$15,602.23	$15,711.96

5. Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight (APC 5722)

For the July 2020 update, the CPT Editorial Panel established two new codes, specifically, CPT codes 0598T and 0599T, to report noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. The codes and their long descriptors are listed in Table 7 (New HCPCS Codes Effective July 1, 2020) above. We note that CMS recently received a new technology application for the MolecuLight i: X procedure, which is described by CPT codes 0598T and 0599T. In determining the appropriate payment for CPT code 0598T, we considered whether there should be separate or conditionally packaged payment for the procedure since the use of the MolecuLight imaging device will most often involve another procedure or service during the same session (for example, debridement of the wound, laboratory service, or another skin-related procedure). In addition, we considered whether the code should be placed in either the Diagnostic Procedures or Minor Procedures APC group. Based on our review of the application and input from our physicians, we assigned CPT code 0598T to APC 5722 ((Level 2 Diagnostic Tests and Related Services)

and status indicator ''T'' with a payment rate of $253.10 effective July 1, 2020. In addition, because CPT code 0599T is an add-on code, we assigned the code to status indicator ''N'' to indicate that the payment is included in the primary procedure. We note that the new technology application indicated a higher projected cost involving care in an operating room (OR), however, based on our review of the MolecuLight service, we removed all OR-associated costs because it is not clear to us that the test would routinely be performed in the OR setting. However, we are soliciting public comments from hospital-based providers that have used MolecuLight on the appropriate OPPS payment, particularly with respect to the cost of providing the service in the hospital outpatient setting as well as the performance of the procedure. We note, as indicated in Table 8 (Comment Timeframe for New and Revised HCPCS Codes), that we are seeking comments on CPT codes that are effective July 1, 2020 in this proposed rule, particularly with respect to the APC and SI assignments, and will finalize them in the CY 2021 OPPS/ASC final rule with comment period.

In summary, we propose to assign CPT code 0598T to APC 5722 (Diagnostic Tests and Related Services) with status indicator ''T'' and CPT code 0599T to status indicator ''N'' for CY 2021. The proposed CY 2021 payment rate for CPT code 0598T can be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

6. Pathogen Test for Platelets/Rapid Bacterial Testing (APC 5732)

For CY 2020, the HCPCS code associated with pathogen test for platelets or rapid bacterial testing was assigned to a new technology APC 1494 (New Technology—Level 1D ($31–$40). For the CY 2021 update, we propose to revise the APC assignment for this HCPCS code from New Technology APC 1494 to clinical APC 5732 (level 2 Minor Procedures). Refer to section III.C. of this proposed rule for the full discussion on the proposal.

7. Urology and Related Services (APCs 5371 Through 5378)

For the CY 2020 OPPS/ASC final rule with comment period (84 FR 61268), we received a public comment suggesting we revise the assignments for the services assigned to the Urology & Related Services APCs. The commenter specifically noted that a reorganization for APCs 5374 through 5376 would be appropriate but added that there are other inconsistencies across services within the urology APCs. We stated in that same final rule that we would consider revisions to the urology APCs in future rulemaking.

Currently, for CY 2020, there are seven levels of APCs for urology services. We have reviewed the CY 2020 geometric mean cost for APCs 5371 through 5377 and, after our analysis of the claims data for this proposed rule, we believe that a modification to the urology APCs is appropriate.

For the CY 2021 OPPS/ASC proposed rule, we evaluated the claims data and noted the large geometric mean cost differential between APC 5376 (level 6) and APC 5377 (level 7) has continued to grow. This differential in the geometric mean cost from APC 5376 to APC 5377 would have been about $9,700, with the geometric mean cost for APC 5377 being about 220 percent of the geometric mean cost of APC 5376. With claims data available for this CY 2021 OPPS proposed rule with comment period showing an unusually large difference between the geometric mean costs of the Level 6 Urology APC and the Level 7 Urology APC on both a dollar and percentage basis, we believe that creating an additional APC in the urology and related series will provide an appropriate structure distinguishing between clinical and cost similarity for the procedures in the different levels. Therefore, for CY 2021, we propose to create an additional urology and related services APC 5378 (level 8) and re-organize the current APC 5376 (level 6) and 5377 (level 7). As a result, we propose a total of eight levels in the urology and related services series. We believe this re-organization would address the lack of an appropriate level for procedures with geometric mean costs that fall between current APC 5376 and current APC 5377.

We note that the proposed re-organization re-assigns CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from the current APC 5376 to APC 5377.

In addition, this proposed revision reassigns the following services from APC 5377 to APC 5378:

- CPT 54416 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session).
- CPT 53444 (Insert tandem cuff).
- CPT 54410 (Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session).
- CPT 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).
- CPT 54401 (Insertion of penile prosthesis; inflatable (self-contained)).
- CPT 54405 (Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir).
- CPT 53447 (Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session).
- CPT 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff).

We note that the APC reassignment for these 10 codes results in geometric mean costs for Levels 6, 7, and 8 of the urology APCs that we believe more appropriately align with the geometric mean costs for services in these APCs than the current structure. Specifically, as listed in Table 19, the geometric mean cost of $8,089.78 for APC 5376, $11,275.15 for APC 5377, and $18,015.54 for APC 5378 reduces the unusually large gaps on both a dollar and percentage basis in geometric mean costs between each APC level.

TABLE 19: PROPOSED CY 2021 GEOMETRIC MEAN COST FOR THE UROLOGY AND RELATED APCS 5371 THROUGH 5378

APC	Group Title	SI	CY 2020 OPPS Geometric Mean Cost	Proposed CY 2021 OPPS Geometric Mean Cost
5371	Level 1 Urology and Related Services	T	$229.83	$262.04
5372	Level 2 Urology and Related Services	T	$544.53	$565.10
5373	Level 3 Urology and Related Services	J1	$1,733.35	$1,758.24
5374	Level 4 Urology and Related Services	J1	$2,953.45	$3,010.01
5375	Level 5 Urology and Related Services	J1	$4,140.38	$4,324.38
5376	Level 6 Urology and Related Services	J1	$7,893.96	$8,089.78
5377	Level 7 Urology and Related Services	J1	$17,195.00	$11,275.15
5378	Level 8 Urology and Related Services	J1	N/A	$18,015.54

In summary, to lessen the large payment gaps on both a dollar and percentage basis between APCs 5376 and 5377, we propose to establish APC 5378 (Level 8 Urology and Related Services) with status indicator ''J1'' for CY 2021. The proposed CY 2021 payment rates for all the urology APCs, specifically APCs 5371 through 5378, can be found in Addendum A to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum A and D1 are available via the internet on the CMS website.

IV. OPPS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices.

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are 7 device categories eligible for pass-through payment: C1823–Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads); C1824–Generator, cardiac contractility modulation (implantable); C1982–Catheter, pressure-generating, one-way valve, intermittently occlusive; C1839–Iris prosthesis; C1734–Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable); C2596–Probe, image-guided, robotic, waterjet ablation; and C1748–Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable).

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021; the pass-through payment status of the device category for HCPCS code C1748 will end on June 30, 2022; and the pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 will end on December 31, 2022. Table 20 shows the expiration of transitional

pass-through payments for these devices. All of these HCPCS codes will have pass-through payment status and will continue to receive pass-through payments in CY 2021.

TABLE 20: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, as discussed in section IV.A.4. of this CY 2021 OPPS/ASC proposed rule, we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of this CY 2021 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at 42 CFR 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing

expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295). Under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that have received FDA marketing authorization, are part of the Breakthrough Devices Program, and meet the other criteria in regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2021

We received five complete applications by the March 1, 2020 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this CY 2021 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2019, two of the applications in the fourth quarter of 2019, and two of the applications in the first quarter of 2020. Two of the applications were approved for device pass-through payment during the quarterly review process: CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope. CUSTOM*FLEX*® ARTIFICIAL*IRIS* received fast-track approval under the alternative pathway effective January 1, 2020. EXALT™ Model D Single-Use Duodenoscope received fast-track approval under the alternative pathway effective July 1, 2020. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope are discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2020 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2022 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*.

A discussion of the applications received by the March 1, 2020 deadline is presented below.

1. Alternative Pathway Device Pass-Through Applications

We received three device pass-through applications by the March 2020 quarterly application deadline for devices that have received FDA marketing authorization and a Breakthrough Device designation from FDA, and therefore are eligible to apply under the alternative pathway. As stated

above in section IV.2.a, under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) CUSTOM*FLEX*® ARTIFICIA*LIRIS*

VEO Ophthalmics submitted an application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* by the June 2019 quarterly deadline. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is described as a foldable iris prosthesis that is custom-made for each individual patient who requires one. The applicant states that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* comes in two models—With Fiber or Fiber Free. The two models are identical in every respect except that the With Fiber model has a polyester meshwork layer embedded in it to provide adequate tear strength to withstand suturing.

The applicant provides that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended to serve as an artificial iris prosthesis, inserted at the time of cataract surgery or during a subsequent stand-alone procedure. The CustomFlexTM Artificial Iris is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The conditions that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* treats are rare; congenital aniridia is present in approximately 1.8 in 100,000 live births (1 in 40,000 to 1 in 100,000),[4-2] congenital IridoCorneal Endothelial Syndrome (ICE) syndrome is even less common (incidence not available). Iris defects such as iatrogenic iridodialysis as a complication of cataract surgery has variable prevalence, ranging from 0–0.84 percent of surgeries,[3 4 5 6 7 8] and may occur in approximately 0.2 percent of blunt orbital trauma.[9] Although rare, these conditions are cosmetically and functionally limiting. The applicant provides that in addition to a noticeably absent or irregular iris/pupil, affected patients frequently experience photophobia (light sensitivity) and glare as well as symptoms such as dry eye.[10 11]

According to the applicant, currently available treatments for symptomatic glare, photophobia, and cosmesis are limited, and an FDA-approved, commercially available iris prosthesis fills a needed gap. Alternatives include tinted spectacles or contact lenses, iris reconstruction (for example, pupilloplasty or iridodialysis repair), and corneal tattooing.[10] Among these, tinted spectacles can provide some symptomatic relief, but the applicant states that they do not address the underlying problem and cannot be used in all settings. Iris reconstruction requires that sufficient iris tissue be present. Tinted contact lenses and corneal tattooing are cosmetically not ideal and have an associated risk of corneal infection (corneal ulcer and infectious keratitis). According to the applicant, in addition, corneal tattooing has risk of surface toxicity, anterior segment inflammation, and/or corneal epithelial defect. The only other artificial iris devices in the U.S. were previously available under FDA compassionate use exemption (Morcher 50F, 96F; Ophtec 311 aniridia lens).[10] However, these devices are no longer available following FDA approval of the CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

With respect to the newness criterion at § 419.66(b)(1), the FDA granted the CUSTOM*FLEX*® ARTIFICIAL*IRIS* premarket approval (PMA) (P170039) on May 30, 2018 for use in the treatment of full or partial aniridia resulting from congenital or acquired defects and was designated a Breakthrough Device by FDA on December 21, 2017. The applicant provided that there was a roughly 3-month market delay after receipt of PMA approval while final labeling in its printed form was submitted to FDA and FDA completed its review and approval process. The applicant notes that commercial availability of the device commenced on September 12, 2018 after it received FDA approval for the final labeling. We received the application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* on May 31, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant states that the device is implanted via injection through a 2.75–4 mm clear corneal incision. Depending on the site of implantation (capsular bag, ciliary sulcus, sutured to sclera), the device is cut (trephined) to the correct diameter. The device can also be sutured to an intraocular lens if an intraocular lens is also implanted at the time of surgery. The applicant further provides that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted. The applicant also claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Upon review, it does not appear that there are any other existing pass-through payment categories that might

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[2] Nelson LB, Spaeth GL, Nowinski TS, et al. Aniridia. A review. Surv Ophthalmol. 1984; 28:621–642.

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[5] Lum F, Schein O, Schachat AP, et al. Initial two years of experience with the AAO National Eyecare Outcomes Network (NEON) cataract surgery database. Ophthalmology. 2000;107:691–697.

[6] Steinberg EP, Tielsch JM, Schein OD, et al. National study of cataract surgery outcomes: Variation in 4-month postoperative outcomes as reflected in multiple outcomes measures Ophthalmology. 1994;101:1131–1140.

[7] Schein OD, Steinberg EP, Javitt JC, et al. Variation in cataract surgery practice and clinical outcomes. Ophthalmology. 1994;101:1142–1152.

[8] Powe NR, Schein OD, Gieser SC, et al. Cataract Patient Outcome Research Team Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. Arch Ophthalmol, 1994;112:239–252.

[9] Kreidl KO, Kim DY, Mansour SE. Prevalence of significant intraocular sequelae in blunt orbital trauma. Am J Emerg Med. 2003 Nov;21(7):525–8.

[10] Weissbart SB, Ayres BD. Management of aniridia and iris defects: an update on iris prosthesis options. Curr Opin Ophthalmol. 2016 May;27(3):244–9.

[11] Lee HJ, Colby KA. A review of the clinical and genetic aspects of aniridia. Semin Ophthalmol. 2013 Sep–Nov;28(5–6):306–12.

apply to the CUSTOMFLEX® ARTIFICIAL*IRIS* and we are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section IV.2.a above, devices that apply under the alternative pathway for devices with a FDA marketing authorization and that have a Breakthrough Device designation are not subject to evaluation for substantial clinical improvement (84 FR 61295). The CUSTOM*FLEX*® ARTIFICIAL*IRIS* received FDA marketing authorization and a Breakthrough Devices designation from FDA on December 21, 2017.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* would be reported with CPT code 66999—Unlisted procedure, anterior segment of eye, which was assigned to APC 5491 (Level 1 Intraocular Procedures) for Calendar Year (CY) 2020. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5491, which had a CY 2019 payment rate of $1,917. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 66999 had a device offset amount of $149.80 at the time the application was received. According to the applicant, the cost of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is $7,700, for both the Fiber Free and with Fiber models.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 402 percent of the applicable APC payment amount for the service related to the category of devices of $1,917 (($7,700/$1,917) × 100 = 402 percent). Therefore, we believe the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 5,140 percent of the cost of the device-related portion of the APC payment amount for the related service of $150 (($7,700/$150) × 100 = 5,140 percent).

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* and the portion of the APC payment amount for the device of $1,917 is 394 percent of the APC payment amount for the related service of $150 (($7,700 − $150)/$1,917) × 100 = 394 percent). Therefore, we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the third cost significance requirement.

We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria discussed in this section, including the cost criterion.

As stated above, we received the application for the CUSTOMFLEX® ARTIFICIAL*IRIS* application by the June 1, 2019 quarterly deadline and preliminarily approved for transitional pass-through payment under the alternative pathway for CY 2020, effective January 1, 2020. We are inviting public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have a FDA Breakthrough Device designation.

(2) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application before the March 2020 quarterly deadline for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope. The EXALT™ Model D Single-Use Duodenoscope is described as a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform endoscopic retrograde cholangiopancreatography (ERCP) procedures by facilitating access to the pancreaticobiliary system. The applicant stated that it has designed the technology of the EXALT™ Model D Single-Use Duodenoscope to eliminate the risk of nosocomial infections due to improper reprocessing of a reusable duodenoscope. As stated above, the EXALT™ Model D Single-Use Duodenoscope is used during ERCP procedures that are performed to examine bile and pancreatic ducts. According to the applicant, the EXALT™ Model D Single-Use Duodenoscope enables passage and manipulation of accessory devices in the pancreaticobiliary system for diagnostic and therapeutic purposes, as necessary. During the ERCP procedure, the physician inserts the duodenscope through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine (duodenum). The applicant stated that during ERCP a cannula is passed through the duodenoscope via a working channel and used to cannulate a small opening on the duodenal wall. Once that step is complete, the physician injects contrast while x-rays are taken to study the bile and/or pancreatic ducts. If the physician identifies an area that warrants further investigation, accessory devices can be inserted through the working channel of the scope and into the pancreaticobiliary system for diagnosis or treatment. According to the applicant, after the conclusion of the procedure, the single-use EXALT™ Model D Single-Use Duodenoscope device has no further medical use and is fully disposable.

With respect to the newness criterion at § 419.66(b)(1), FDA granted 510(k) premarket clearance (K193202) as of December 13, 2019. Prior to 510(k) clearance, the applicant received Breakthrough Device designation from FDA on November 19, 2019. We received the application for a new device category for transitional pass-

through payment status for the EXALT™ Model D Single-Use Duodenoscope on January 17, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

With regard to the eligibility criterion at § 419.66(b)(3), according to the applicant, the EXALT™ Model D Single-Use Duodenoscope is integral to the ERCP service provided, is used for one patient only, and is surgically inserted as it is inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The applicant also stated that the EXALT™ Model D Single-Use Duodenoscope meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes EXALT™ Model D Single-Use Duodenoscope, the applicant suggested a category descriptor of ''Duodenoscope, single-use.'' The applicant also provided an existing device category ''C1749, Endoscope, retrograde imaging/illumination colonoscope device (implantable),'' for pass-through payment for another endoscope and explained why they believe the category descriptor is not applicable to EXALT™ Model D Single-Use Duodenoscope. The applicant stated that HCPCS C1749 does not appropriately describe the EXALT Model D, as C1749 is intended to describe endoscopic imaging devices that are inserted through a colonoscope and into the colon. The applicant argues that EXALT Model D is the first and only single-use duodenoscope through which devices can be passed, and it is utilized in ERCP procedures. The applicant further states that the scope that is the subject of this request provides access to a different part of the anatomy, specifically, the pancreaticobiliary system and facilitates access for diagnostic and therapeutic purposes, as opposed to the devices described by C1749, which are endoscopic imaging devices that are inserted through a colonscope and into the colon, providing access to a different part of the anatomy. Upon review, we agree with the applicant that it does not appear that there are any other existing pass-through payment categories that might apply and we are inviting public comment on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As previously discussed in section 2.a above, we finalized the alternative pathway for devices that receive FDA marketing authorization and are granted a Breakthrough Device designation in the CY 2020 OPPS/ASC final rule (84 FR 61295). The EXALT™ Model D Single-Use Duodenoscope has marketing authorization and a Breakthrough Device designation from the FDA and therefore is not evaluated based on substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the EXALT™ Model D Single-Use Duodenoscope would be reported with CPT code 43274 which is associated with APC 5331 (Complex GI Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We used APC 5331 for our calculations, which had a CY 2020 payment rate of $4,780.30 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 43274 had a device offset amount of $1,287.81 at the time the application was received. According to the applicant, the cost of the EXALT™ Model D Single-Use Duodenoscope is $2,930.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 61 percent of the applicable APC payment amount for the service related to the category of devices of $4,780.30 ($2,930/$4,780.30 × 100 = 61.3 percent). Therefore, we believe the EXALT™ Model D Single-Use Duodenoscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 228 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,287.81 ($2,930/$1,287.81) × 100 = 227.5 percent. Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope and the portion of the APC payment amount for the device of $1,287.81 is 34 percent of the APC payment amount for the related service of $4,780.30 (($2,930 − $1,287.81)/$4,780.30) × 100 = 34.4 percent). Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the third cost significance requirement. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the device pass-

through payment criteria discussed in this section, including the cost criterion.

As specified above, the EXALT™ Model D Single-Use Duodenoscope application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2020. We are inviting public comment on whether the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have a FDA Breakthrough Device designation.

(3) BAROSTIM NEO™ System

CVRx, Inc. submitted an application for the BAROSTIM NEO™ System by the December 2019 quarterly deadline. The applicant provides that the BAROSTIM NEO™ is indicated for the treatment of symptoms of patients with advanced heart failure. The applicant asserts that the BAROSTIM therapy triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. According to the applicant, increased sympathetic and decreased parasympathetic activity contribute to heart failure (HF) symptoms and disease progression. Barostim's mechanism of action is stimulating the carotid baroreceptor which results in centrally mediated reduction of sympathetic and increase in parasympathetic activity. A single 2mm coated electrode with a 7mm silicone backer is sutured to the carotid artery to activate the baroreceptors. It is connected to an implantable pulse generator in the chest which provides control of baroreflex activation energy. The BAROSTIM NEO™ System uses CVRx patented BAROSTIM THERAPY™ technology to trigger the body's own natural systems (baroreflex) by electrically activating the carotid baroreceptors, the body's natural cardiovascular regulation sensors.

According to the applicant, in conditions such as hypertension and heart failure, it is believed the baroreceptors, the body's natural sensors, are not functioning properly and are not sending sufficient signals to the brain. This results in the brain sending signals to other parts of the body (heart, blood vessels, kidneys) to constrict the blood vessels, retain water and salt by the kidneys and increase stress-related hormones. The applicant provides that when the baroreceptors are activated by the BAROSTIM NEO™ system, signals are sent through neural pathways to the brain. In response, the brain works to counteract this stimulation by sending signals to other parts of the body (heart, blood vessels, and kidneys) that relax the blood vessels and inhibit the production of stress-related hormones. These changes act to reduce cardiac after-load and enable the heart to increase blood output, while maintaining or reducing its workload. Parameters are programmed into the Implantable Pulse Generator (IPG) using telemetry via a wireless external programming system. The applicant states that the BAROSTIM NEO™ System is fully programmable to adjust the therapy to each patient's need.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted the BAROSTIM NEO™ System a premarket approval (P180050) and a Breakthrough Device designation on August 16, 2019 for the improvement of symptoms of heart failure—quality of life, six-minute hall walk, and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35 percent, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines. We received the application for a new device category for transitional pass-through payment status for the BAROSTIM NEO™ on November 27, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the BAROSTIM NEO™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of BAROSTIM NEO™ is integral to the service of providing baroflex therapy™, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed the BAROSTIM NEO™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the BAROSTIM NEO™ meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes BAROSTIM NEO™, the applicant suggested a category descriptor of ''Generator, neurostimulator (implantable), non-rechargeable with carotid sinus stimulation lead.'' The applicant also provided a list of current and expired device categories for pass-through payment for other neurostimulation systems and their rationale for why they believe the category descriptors are not applicable to BAROSTIM NEO™.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1767, Generator, neurostimulator (implantable), non-rechargeable. The applicant stated that similar to the traditional spinal cord stimulation (SCS) systems included in this category, the BAROSTIM NEO™ System is not rechargeable; however, it is the only system that works to deliver CVRx's proprietary baroreflex activation therapy (BAT). The applicant provided that BAT uses afferent signaling to the brain by stimulating the carotid artery to reduce the sympathetic signal and increase the parasympathetic signal. The applicant stated that this unique therapy works to rebalance the autonomic input to the heart to improve heart failure symptoms.

Additionally, the applicant stated that traditional devices provide pain relief by disrupting the pain signals traveling between the spinal cord's nervous system and the brain, but the BAROSTIM NEO System uses the generator to stimulate the baroreceptors in the carotid artery to treat the symptoms of patients with advanced heart failure. The applicant stated that the BAROSTIM NEO generator is unique in its capability to drive electricity up to 20 mA/100 Hz with sufficient battery capacity to provide the required therapy through the BAROSTIM NEO™ carotid sinus lead. The applicant described that the BAROSTIM NEO™ carotid sinus lead is sutured to the carotid wall, where the baroreceptors (stretch fibers) are located. Electrical current radiating from the carotid sinus lead activates the baroreceptors. When activated, the baroreceptors send efferent signals through the Carotid Sinus Nerve to the brain. The brain interprets these afferent signals and reacts by reducing the sympathetic tone and increasing the parasympathetic tone. The applicant states that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the

symptoms of patients with advanced heart failure.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads. The applicant states that existing device category C1823 is exclusively used to describe a complete system comprised of a generator implanted in the chest, a stimulation lead attached to the phrenic nerve and a sensing lead to control the function of the diaphragm for the treatment of moderate to severe central sleep apnea. The applicant states that the BAROSTIM NEO™ System utilizes a single stimulation lead positioned on the carotid artery to stimulate baroreceptors. The stimulation of the baroreceptors creates afferent nerve traffic through the Carotid Sinus Nerve, and results in the activation of the baroreflex. The applicant again states that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to improve quality of life and functional status in heart failure.

The applicant also provided that BAROSTIM NEO™ is not described by existing device category C1778, Lead, neurostimulator (implantable). The applicant stated that leads used in traditional neurostimulation are implanted on nerves (for example, spinal cord, peripheral nerves). The applicant stated that in contrast, the BAROSTIM NEO carotid sinus lead is sutured onto the carotid artery and is the only lead that is designed to be secured on an arterial wall to stimulate sensors located inside the arterial wall (baroreceptors). The applicant provided that stimulation is delivered to the arterial wall, where the baroreceptors (stretch fibers) are located. The applicant stated that the BAROSTIM NEO™ generator is uniquely designed to send electric current via the BAROSTIM NEO™ carotid sinus lead and that the BAROSTIM NEO™ carotid sinus lead is uniquely designed to only interface with the BAROSTIM NEO generator. Again, the applicant provided that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

We are concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment categories. Specifically, we believe that Barostim may be appropriately described by C1767 as the Barostim device consists of a generator, a neurostimulator, and a lead. We are inviting public comment on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section 2.a above, devices that apply under the alternative pathway for devices with a FDA marketing authorization and that have a Breakthrough Device designation are not subject to evaluation for substantial clinical improvement (84 FR 61295). Barostim has FDA marketing authorization and a Breakthrough Device designation.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the BAROSTIM NEO™ would be reported with CPT code 0266T, which they consider to be a total system code. CPT code 0266T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which has a CY 2020 payment rate of $29,115.50. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0266T had a device offset amount of $24,253 at the time the application was received. According to the applicant, the cost of the BAROSTIM NEO™ is $35,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 120 percent of the applicable APC payment amount for the service related to the category of devices of $29,116 (($35,000/29,116) × 100 = 120.2 percent). Therefore, we believe the BAROSTIM NEO™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 144 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,253 (($35,000/$24,253) × 100 = 144.3 percent). Therefore, we believe that the BAROSTIM NEO™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $35,000 for BAROSTIM NEO™ and the portion of the APC payment amount for the device of $24,253 is 37 percent of the APC payment amount for the related service of $29,116 (($35,000 − $24,253)/$29,116) × 100 = 36.9 percent). Therefore, we believe that the BAROSTIM NEO™ System meets the third cost significance requirement.

We are inviting public comment on whether the BAROSTIM NEO™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

2. Traditional Device Pass-Through Applications

(1) Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat (Hemospray) for CY 2021. Hemospray® Endoscopic Hemostat is a prescription use device consisting of a hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder, naturally sourced from aluminum phyllosilicate clay, developed for endoscopic hemostasis.

According to the applicant, Hemospray® is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray® powder is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. Bentonite can absorb five to ten times its weight in water and swell up to 15 times its dry volume. Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue, forming a physical barrier to aqueous fluid (for example, blood). Hemospray® is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray® is single-use and disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the Hemospray® Endoscopic Hemostat (Hemospray®) as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on May 7, 2018. We received the application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat on December 2, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether Hemospray® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Hemospray® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that Hemospray® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether Hemospray® meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not yet identified an existing pass-through payment category that describes Hemospray®. We are inviting public comment on whether Hemospray® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. The applicant stated that Hemospray® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Hemospray® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality.

According to the applicant, Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it stated Hemospray® would provide a substantial clinical improvement: (1) As a primary treatment or a rescue treatment after the failure of a conventional method, and (2) in use for the treatment of malignant lesions. The applicant provided seven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

The first article provided by the applicant was a prospective single armed multicenter phase two safety and efficacy study performed in France.[15] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray® was used as either a first line treatment (46.5 percent) or salvage therapy (53.5 percent) following unsuccessful treatment with another method. The indication for Hemospray® as a first-line therapy or salvage therapy was at the discretion of the endoscopist. Of the 202 patients, the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: Ulcers (37.1 percent), malignant lesions (30.2 percent), post-endoscopic bleeding (17.3 percent), and other (15.3 percent). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[6] [7] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30 the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray® was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray® was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray® are due to its threefold mechanism of action: formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[8] No severe adverse events

[5] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[6] Ibid.

[7] ASA House of Delegates/Executive Committee. (2014, October 15). *ASA Physical Status Classification System*. Retrieved from American Society of Anesthesiologists: *https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system*

[8] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

were noted, however the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray® was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

The applicant provided a second article consisting of an abstract from another systematic review article.[9] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray® as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69; 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities, in nonvariceal gastrointestinal bleeding, Hemospray® seems to have significantly higher rates of immediate hemostasis.

A third article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[10] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembled and delivery of Hemospray® to a bleeding lesion, was 97.7 percent (95.1 percent–99.2 percent). The most common causes of bleeding in patients were peptic ulcer (28 percent), malignancy (18.4 percent), therapeutic endoscopy-related (17.6 percent), and surgical anastomosis (8.8 percent). Overall, 93.5 percent (89.5 percent to 96 percent) of procedures achieved hemostasis. Recurrent bleeding, defined as (1) a new episode of bleeding symptoms, (2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or >3g/dL in 24 hours, or (3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9 percent–21 percent) and 22.9 percent (17.8 percent–28.3 percent) respectively. The overall risk of Hemospray® failure at 3 and 30 days was 21.1 percent (16.4 percent–26.2 percent) and 27.4 percent (22.1 percent–32.9 percent) respectively with no statistically significant differences (p = 0.07) between causes at 30 days (for example, peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24–3.13)), hypotension vs. normotensive (sHR 2.14 (1.22–3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10–2.95)) were independently associated with Hemospray® failure. The overall 30-day survival was 81.9 percent (76.5 percent–86.1 percent) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; twenty patients (7.6 percent) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray® failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray® is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fourth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray®.[11] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray® application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most common pathologies of peptic ulcer (53 percent), malignancy (16 percent), post-endoscopic bleeding (16 percent), bleeding from severe inflammation (11 percent), esophageal variceal bleeding (2.5 percent), and cases with no obvious cause (1.6 percent). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[12] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[13] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray®; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10–1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03–1.25)). At 30 days the all-cause mortality was 20.1 percent with 78 percent of these patients having achieved immediate endoscopic hemostasis and a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4 percent, p = 0.04) as compared to all other groups. According to the authors, in comparison to major recent studies they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[14] The authors further note limitations in that the inclusion of patients was nonconsecutive and at the discretion of the endoscopist, at the time of the endoscopy, which allows for the potential introduction of selection bias, which may have affected these study results.

[9] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: analyzing the efficacy of hemostatic nanopowder (TC–325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S–741.

[10] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et. al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[11] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[12] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: *https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults.*

[13] Ibid.

[14] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

The fourth article also described the utility of Hemospray® in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[15] [16] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fourth article, the applicant noted that 50 patients were treated for malignant bleeding with an overall immediate hemostasis in 94 percent of patients.[17] Of the 50 patients, 33 were treated with Hemospray® alone, 11 were treated with Hemospray® as the final treatment, and 4 were treated with Hemospray® as a rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[18] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray® was used as a primary treatment as compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[19] The applicant concluded that Hemospray® may provide an advantage as a primary treatment to patients with malignant bleeding.

The applicant provided a fifth article, which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray® versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[20] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and 180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45 percent) or 3 (40 percent). Immediate hemostasis was achieved in 90 percent of Hemospray® patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray® treatment. One patient died while being treated with Hemospray® from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray® initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray® group (20 percent) as compared to the control group (60 percent) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray® prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray®.

A sixth article provided by the applicant was a case-controlled study with 10 patients with active upper gastrointestinal bleeding from tumor compared with 10 conventional therapy patients selected as historical controls, matched by type of tumor.[21] The study evaluated efficacy for tumor-related bleeding and compared Hemospray® to conventional therapies, specifically examining 14-day rebleeding rates, lengths of hospital stay (LOS), and mortality rate at 30-day follow up. Historical controls were selected from patient medical records from 2010 to 2014. Among the patients who received Hemospray®, the 14-day rebleeding rate (10 percent vs. 30 percent; P = 0.60). and the 30-day mortality rates (10 percent vs. 30 percent, P = 0.7) were three times lower compared to the control group; neither rate was statistically significant. There was no difference in LOS between the Hemospray® and conventional therapy patients.

A seventh article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[22] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray® and recurrent bleeding was suspected if one of seven criteria were met: (1) Hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co-morbid illness, and 25 percent were on current antiplatelet/anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred among 13 of 86 (15 percent) and 1 of 53 (1.9 percent) at 3 and 30 days, respectively. A total of 25 patients (28.4 percent) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found patients with good performance status, no end-

[15] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[16] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[17] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[18] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[19] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[20] Chen Y–I, Wyse J, Lu Y, Martel M, Barkun AN, TC–325 hemostatic powder versus current standard of care in managing malignant GI bleeding: a pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: *https://doi.org/10.1016/j.gie.2019.08.005*.

[21] Pittayanon, R., Prueksapanich, P., & Rerknimitr, R. (2016). The efficacy of Hemospray in patients with upper gastrointestinal bleeding from tumor. Endoscopy international open, 4(09), E933–E936.

[22] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignant GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991–1002.

stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray® treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques and state this implies that Hemospray® does not differ from conventional techniques and remains unsatisfactory.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant stated Hemospray® is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used to rescue patients who have failed more conventional endoscopic modalities. Furthermore, the applicant stated that in patients with malignant bleeding in the GI tract, Hemospray® provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which, in combination with definitive cancer treatment, may lead to improvements in long term survival. Lastly, the applicant stated Hemospray® is an important new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

We note that the majority of studies provided lack a comparator when assessing the effectiveness of Hemospray®. Three of the articles provided are systematic reviews of the literature. While we find these articles helpful in establishing a background for the use of Hemospray®, we are concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appear to be single-armed studies assessing the efficacy of Hemospray® in the patient setting. In all of these articles, comparisons are made between Hemospray® and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it is difficult to determine if any differences seen result from Hemospray® or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appears to potentially be introduced in that providers may be allowed to select the manner and order in which patients are treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appears to be in the process of peer-review and is not yet published. Furthermore, this article is written as a feasibility study for a potentially larger randomized control trial and contains a sample of only 20 patients. This small sample size leaves us concerned that the results are not representative of the larger Medicare population. Lastly, as described we are concerned the control group can receive one of multiple treatments which lack a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant is not an acceptable treatment for endoscopic bleeding. Accordingly, it is not clear whether performance seen in the treated group as compared to the control group is due to Hemospray® itself or due to confounding factors.

Third, we are concerned with the samples chosen in many of the studies presented. Firstly, the Medicare population is approximately 54 percent female and 46 percent male.[23] Many of the samples provided by the applicant are overwhelmingly male. Secondly, many of the studies provided were performed in European and other settings outside of the United States. We are therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we are concerned about the potential for adverse events resulting from Hemospray®. It is unclear from the literature provided by the applicant what the likelihood of these events is and whether or not an evaluation for the safety of Hemospray® was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray®. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles mention the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article[24] recorded adverse events related to Hemospray®, including abdominal distention and esophageal perforation.

According to information submitted by the applicant, Cook Medical is voluntarily recalling Hemospray® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases has cracked or broken when the device is activated and in some cases has caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical has received 1 report of a superficial laceration to the user's hand that required basic first aid; however, there have been no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical has initiated an investigation and will determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall does restrict availability of the device, they wish to continue their application as they believe the use of Hemospray® significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

Based upon the evidence presented, we are inviting public comments on whether the Hemospray® Endoscopic Hemostat meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Hemospray® would be reported with HCPCS codes 43227, 43255, 44366, 44378, 44391, 45334, and 45382. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5312, which had a CY 2020 payment rate of $1,004.10 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR

[23] *https://www.cms.gov/files/document/2018-mdcr-enroll-ab-5.pdf.*

[24] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et. al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

79657). HCPCS code 45382 had a device offset amount of $33.54 at the time the application was received. According to the applicant, the cost of the Hemospray® Endoscopic Hemostat is $2,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,500 for Hemospray® is 249 percent of the applicable APC payment amount for the service related to the category of devices of $1004.10 (($2,500/$1,004.10) × 100 = 249 percent). Therefore, we believe Hemospray® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,500 for Hemospray® is 7,454 percent of the cost of the device-related portion of the APC payment amount for the related service of $33.54 (($2,500/$33.54) × 100 = 7,453.8 percent). Therefore, we believe that Hemospray® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for Hemospray® and the portion of the APC payment amount for the device of $33.54 is 246 percent of the APC payment amount for the related service of $1004.10 t ((($2,500 − $33.54)/$ 1,004.10) × 100 = 245.6 percent). Therefore, we believe that Hemospray® meets the third cost significance requirement.

We are inviting public comment on whether the Hemospray® Endoscopic Hemostat meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) The SpineJack® Expansion Kit

Stryker, Inc., submitted an application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) by the March 2020 quarterly deadline. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes: 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded). The applicant explained implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required. Additionally, the applicant explained that titanium alloy allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant stated that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[25]

The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for a progressive and controlled reduction of the vertebral fracture.[26] The applicant stated that when expanded, each SpineJack® implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[27]

The applicant further explained that the expansion of the SpineJack® implants creates a preferential direction of flow for the bone cement and once the desired expansion has been obtained, polymethylmethacrylate (PMMA) bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant stated that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass,[28] which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[29] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[30] and of these VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[31] Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times

[25] Vanni D et al. ''Third-generation percutaneous vertebral augmentation systems.'' *Journal of Spine Surgery.* 2016, vol 2(1), pp. 13–20.

[26] Vanni D., et al., ''Third-generation percutaneous vertebral augmentation systems,'' *J. Spine Surg.,* 2016, vol. 2(1) pp. 13–20.

[27] Noriega D. et al., ''Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study,'' *BioMed Res. Int.,* 2015, vol. 173872.

[28] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: *https://www.nof.org/patients/what-is-osteoporosis/.*

[29] King A and Fiorentino D. ''Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures.'' *Health Affairs (Millwood),* 2011, vol. 30(12), pp. 2362–2370.

[30] Riggs B and Melton L. ''The worldwide problem of osteoporosis: Insights afforded by epidemiology.'' *Bone,* 1995, vol. 17(Suppl 5), pp. 505–511.

[31] Siemionow K and Lieberman I. ''Vertebral augmentation in osteoporotic and osteolytic fractures: Current Opinion in Supportive and Palliative Care.'' 2009, vol. 3(3), pp. 219–225.

greater than the general population.[32] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[33]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity, and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant explained that the SpineJack® implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral ''struts'' that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n = 1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the United States between 2005 and 2010 were BKP.[34] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[35]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[36]

The applicant provided additional detail comparing the construction and mechanism of action for other VA treatments, provided below. According to the applicant the Kiva® system is constructed of a nitinol coil and PEEK–OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded) and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK–OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum height of 15 mm. The applicant stated that the lifting direction of the Kiva implant is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[37]

[32] Wong C and McGirt M. ''Vertebral compression fractures: A review of current management and multimodal therapy.'' *Journal of Multidisciplinary Healthcare,* 2013, vol 6, pp. 205–214.

[33] Burge R et al. ''Incidence and economic burden of osteoporosis-related fractures in the United States: 2005–2025.'' *Journal of Bone and Mineral Research.* 2007, vol 22(3), pp. 465–475.

[34] Goz V et al. ''Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010.'' *The Spine Journal.* 2015, vol. 15(5), pp. 959–965.

[35] Lin M. ''Minimally invasive vertebral compression fracture treatments. *Medtech 360, Market Insights, Millennium Research Group.* 2019.

[36] Ibid.

[37] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine.* 2015; 40(12):865–875.

Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200–500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[38]

The applicant summarized the differences and similarities of the SpineJack®, BKP, and PEEK coiled implant as follows: (1) With respect to construction, SpineJack® is made of Titanium-6-Aluminum-4-Vanadium compared to thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, SpineJack® and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, SpineJack® allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, SpineJack® provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, SpineJack® provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. We received the application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit on February 4, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the SpineJack® Expansion Kit meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the SpineJack® Expansion Kit is integral to the service of reducing painful osteoporotic vertebral compression fractures (VCFs), is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, the implants remain within the VB with the delivered bone cement. The applicant also claimed the SpineJack® Expansion Kit meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the SpineJack® Expansion Kit meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the SpineJack® Expansion Kit as an implantable fracture reduction system used to treat vertebral compression fractures (VCFs). The applicant reported that it does not believe that the SpineJack® Expansion Kit is described by an existing category and requested category descriptor ''Vertebral body height restoration device, scissor jack (implantable).'' We have identified one existing pass-through payment categories that may be applicable to SpineJack® Expansion Kit. The SpineJack® Expansion Kit may be described by HCPCS code C1821 (interspinous process distraction device (implantable)). We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. With respect to the substantial clinical improvement criterion, the applicant submitted 8 studies and 19 other references to support assertions that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant stated are clinically significant adverse events associated with osteoporotic VCF. The applicant also stated that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as a result, the SpineJack® implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study[39] in support of multiple

[38] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. *Clinical Biomechanics.* 2012; 27(4):346–353.

[39] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures

Continued

substantial clinical improvement claims: Reduction in adjacent level fractures, superiority in mid-vertebral body height restoration, and pain relief. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) Reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure; (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline; and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ–5D) index score (to evaluate quality of life), EQ–VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints, and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either SpineJack® or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including: (1) At least 50 years of age; (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 months, due to osteoporosis; (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15 percent but ≤40 percent; and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70 percent mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to SpineJack® and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (SpineJack® system or BKP) were age 65 or older. The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable for the SpineJack® system 510(k) clearance, including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for SpineJack® and BKP respectively ($p = 0.0016$). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for SpineJack® compared to BKP at both 6 months (88.1 percent vs. 60.9 percent; $p < 0.0001$) and 12 months (79.7 percent vs. 59.3 percent; $p < 0.0001$). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with SpineJack® than BKP at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; $p = 0.0246$) and at 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; $p = 0.0035$), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® group compared to the BKP group at 1 month ($p = 0.029$) and 6 months ($p = 0.021$). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90 percent in the SpineJack® group and ≥80 percent in the BKP group, with a statistically significant difference in favor of SpineJack® at 1-month post-procedure (93.8 percent vs 81.4 percent; $p = 0.03$). The study also reported: (1) No statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and (3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3 percent for TIVAD, 41.0 percent for BKP; $p = 0.436$). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate of adjacent fractures more than double the SpineJack® group (27.3 percent vs. 12.9 percent; $p = 0.043$). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® group (21.9 percent vs. 7.4 percent) (a p-value was not reported for this result). The most common AEs reported over the study period were backpain (11.8 percent with SpineJack®, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with SpineJack®, 12.3 percent with

(SAKOS study),'' *The Spine Journal,* 2019, vol. 19(11), pp. 1782–1795.

BKP), and new thoracic vertebral fractures (7.4 percent with SpineJack®, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with SpineJack®; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with SpineJack®, 9.6 percent with BKP). We also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® group and 3.3 ± 2.4 days for the BKP group (p = 0.926, Wilcoxon test).

The applicant also submitted additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant stated that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by Lindsay et al.[40] and Ross et al.[41] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant stated that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP (p < 0.0001) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant stated the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; p = 0.043) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also stated superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[42] According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further stated that by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[43] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; p = 0.0246) and 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; p = 0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[44] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to SpineJack® (n = 15) or BKP (n = 15).[45] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[46] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[47] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height (10 ± 13 percent vs 2 ± 8 percent for BKP, p = 0.007) and midline VB height (10 ± 11 percent vs 3 ± 7 percent for BKP, p = 0.034), while there was a larger correction of the VB angle (− 4.97° ± 5.06° vs 0.42° ± 3.43°; p = 0.003) for the SpineJack® group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant stated that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported an observational case series (with no comparison group) of SpineJack®. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[48] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® device, the VB height significantly increased to 1.9 cm (SD of 0.64; p < 0.01), but was reduced to 1.8 cm (SD of 0.61; p < 0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al., these results were specifically for mean anterior VB height. The study does not

[40] Lindsay R. et al., ''Risk of new vertebral fracture in the year following a fracture,'' *Journal of the American Medical Association,* 2001, vol. 285(3), pp. 320–323.

[41] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Annals of Internal Medicine.* 1991, vol. 114(11), pp. 919–923.

[42] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. *World Neurosurgery.* 2016; 90:391–396.

[43] Tzermiadianos M., et al., ''Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture,'' *European Spine Journal,* 2008, vol. 17(11), pp. 1522–1530.

[44] Noriega D., et al., ''Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study,'' *Osteoporosis International,* 2019, vol. 30, pp. 637–645.

[45] Ibid.

[46] Ibid.

[47] Ibid.

[48] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

appear to report results for midline VB height.[49] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was −1° (SD of 5.8), which increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® device, KA significantly decreased to 10.8° (SD of 9.1; $p < 0.01$); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; $p < 0.01$).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[50] The applicant stated that the radiologic outcomes from this study were: (1) The mean KA and mean KA restoration were more efficient after SpineJack® than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration were more favorable after SpineJack® than VP.[51] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[52] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (twenty-seven vertebrae were treated with SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al. (2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (twelve treated with SpineJack® and twelve treated with BKP). The applicant stated that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) Height restoration was significantly better for the SpineJack® group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[53] The applicant stated that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[54]

The applicant also stated that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system. The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial: (1) Progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month ($p = 0.029$) and 6 months ($p = 0.021$); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8 percent vs 81.5 percent; $p = 0.030$). The applicant also noted that although continued pain score improvements were seen out to 1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance ($p = 0.061$). The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central analgesic agent medications in the SpineJack® implant-treated group as compared to those in the BKP-treated group (SJ 7.4 percent vs. BKP 21.9 percent, $p = 0.015$). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSAIDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[55] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n = 81), or traumatic VCF with associated osteoporosis (n = 22) who had a SpineJack® procedure. Twenty-three patients withdrew from the study before the 12-month visit. The study reported a significant improvement in back pain at 48 hours after SpineJack® procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4 ± 1.3 cm (mean change: −5.2 ± 2.7 cm; $p < 0.001$) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF

[49] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

[50] Lin J., et al., ''Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: a 1-Year Follow-up Study,'' *World Neurosurg.* 2016, vol. 60, pp. 391–396.

[51] Ibid.

[52] Kruger A., et al., ''Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used,'' *Clinical Biomechanics,* 2013, vol. 28, pp. 725–730; and Kruger A., et al., ''Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: a cadaveric study,'' *The Spine Journal,* 2015, vol. 15, pp. 1092–1098.

[53] Ibid.

[54] Ibid.

[55] Noriega D., et al., ''Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study.'' *BioMed Research International.* 2015, 173872.

and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of −5.5 (SD = 1.9) (median relative change of 81.0 percent) ($p < 0.001$) at 48 hours post-surgery (n = 22), and −5.7 (SD = 2.3) mean change (90.3 percent median relative change) ($p < 0.001$) at 12 months (n = 16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months. The applicant summarized that (1) Pain relief and improvements in pain scores were statistically significant immediately after treatment (48–72 hours) and at 6 and 12 months following surgery ($p < 0.001$); and (2) the mean improvement between baseline and at 48–72 hours after the procedure (n = 31) was −4.6 (2.6) ($p < 0.001$), while the mean improvement between baseline and at the 12-month follow-up (n = 22) was −6.0 (3.4) ($p < 0.001$). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[56] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® devices (no comparison procedure).[57] The applicant summarized that: (1) Pain relief was statistically significant ($p < 0.001$), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

We note that the results of the SAKOS trial do not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, there appears to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Furthermore, there appears to be a lack of data comparing the SpineJack® system to conservative medical therapy. We note there is an active study posted on *clinicaltrials.gov* comparing SpineJack® system to conservative orthopedic management consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The clinicaltrials.gov entry indicates that findings should be forthcoming in 2020. Additionally, we note that the recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)), do not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[58] The ASBMR recommended more rigorous study of treatment options including ''larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events).''

We are inviting public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the SpineJack® system would be reported with CPT code 22513, which is assigned to APC 5114 (Level 4 Musculoskeletal Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5114, which has a CY 2019 payment rate of $5,891.95. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 22513 had a device offset amount of $1,127 at the time the application was received. According to the applicant, the cost of the SpineJack® system is $5,623.[59]

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 94 percent of the applicable APC payment amount for the service related to the category of devices of SpineJack® system (($5,622.64/$5,981.28) × 100 = 94 percent). Therefore, we believe the SpineJack® system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 499 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,126.87(($5,622.64/$1,126.87) × 100 = 499 percent). Therefore, we believe that the SpineJack® system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,622.64 for the SpineJack® system and the portion of the APC payment amount for the device of $1,126.87 is 75 percent of the APC payment amount for the related service of $5,987.28 (($5,622.64 − $1,126.87)/$5,981.28) = 75.2 percent). Therefore, we believe that the SpineJack® Expansion Kit meets the third cost significance requirement.

We are inviting public comment on whether the SpineJack® Expansion Kit meets the device pass-through payment

[56] Ibid.

[57] Renaud C., ''Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients.'' *Orthopaedics & Traumatology: Surgery & Research,* 2015, vol. 101, pp. 857–859.

[58] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., ''Percutaneous vertebroplasty for osteoporotic vertebral compression fracture,'' *Cochrane Database Syst Rev.* 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., ''The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report.'' *J Bone Miner Res.,* 2019, vol. 34(1), pp. 3–21.

[59]

criteria discussed in this section, including the cost criterion.

3. Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Certain Transformative New Devices

As described previously, in the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295 through 61297). Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Similarly, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval for IPPS new technology add-on payments under this alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). Because of this potential confusion, we clarified in the FY 2021 IPPS/LTCH PPS proposed rule that an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices (85 FR 32692).

We are clarifying in this proposed rule that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, we are clarifying that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and we are making a conforming change to the regulations at 419.66(c)(2). We also note that the transitional pass-through payment application for the device must be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay) for the device for the indication covered by the Breakthrough Devices Program designation.

In summary, in this CY 2021 OPPS/ASC proposed rule, we propose to amend the regulations in § 419.66(c)(2)(ii) to state that ''A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.''

4. Comment Solicitation on Continuing To Provide Separate Payment in CYs 2022 and Future Years for Devices With OPPS Device Pass-Through Payment Status During the COVID–19 Public Health Emergency (PHE)

In this proposed rule, we are soliciting comments on whether we should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE, and if so, how we should implement that adjustment and for how long the adjustment should apply. On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020 [60] under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020 and again effective July 25, 2020, the determination that a PHE exists.[61] On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the United States constitutes a national emergency,[62] retroactive to March 1, 2020. Due to the PHE, we received multiple inquiries from stakeholders regarding potential adjustments to the pass-through payment for devices with OPPS transitional pass-through payment status that may be impacted by the PHE. According to stakeholders, healthcare resources have been triaged to assist in the COVID–19 pandemic response effort, which has reduced utilization for devices receiving transitional pass-through payment, particularly for devices used in services that could be considered elective. Stakeholders cited the CMS recommendations issued on March 18, 2020 to postpone elective surgeries due to the COVID–19 PHE.[63] Stakeholders claim that devices on pass-through status are frequently used during such elective procedures, and that CMS's ability to calculate appropriate payment for services that include these devices once the devices transition off of pass-through status could be hindered by a reduction in claims being submitted with these devices during the PHE.

Transitional pass-through payment for devices is described in section 1833(t)(6) of the Act. It is intended as an interim measure to allow for adequate payment of new innovative technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). As previously stated, transitional pass-through payments for devices can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the device.

In response to stakeholder concerns regarding reduced utilization of procedures that include pass-through devices during the PHE, we are specifically requesting public comment on utilizing our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for these devices in order to account for the period of time that utilization for the devices was reduced due to the PHE. Any rulemaking on this issue in response to this comment solicitation would be included in the CY 2022 OPPS/ASC proposed rule and would consider the impact of the PHE on devices with OPPS device pass-through payment status during the PHE. Note that OPPS device pass-through payment status generally lasts three years, and none of the devices with less than three years of pass-through payment status at the start of the PHE have pass-through payment status set to end before December 31st, 2021.

[60] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[61] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[62] *https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.*

[63] *https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental.*

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this CY 2021 OPPS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APCs were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of APC assignment.

Under our existing policy, procedures that meet the criteria listed below in section IV.B.1.b. of this CY 2021 OPPS/ASC proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of the CY 2021 OPPS/ASC proposed rule, respectively.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices

are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare &

Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

In response to stakeholder requests for additional detail on our device-intensive methodology, we have updated our claims accounting narrative with a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2021 OPPS/ASC proposed rule on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2021, we are not proposing any changes to our device-intensive policy.

The full listing of the proposed CY 2021 device-intensive procedures can be found in Addendum P to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We are not proposing any changes to this policy for CY 2021.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. Although we adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual, we inadvertently did not make conforming changes to the regulation text. In particular, we did not change our regulation at 42 CFR 419.45(b)(1) and (2), which describes the amount of the reduction in the APC payment in situations where the beneficiary receives an implanted device that is replaced without cost to the provider or the beneficiary or where the provider receives a full or partial credit for the cost of a replaced device and which continues to state that the amount of the reduction is the device offset amount. Therefore, in this CY 2021 OPPS/ASC proposed rule, we are changing our regulation at § 419.45(b)(1) and (2) to conform with the policy we adopted in CY 2014. In particular, we are revising our regulations at § 419.45(b)(1) to state that, for situations in which a beneficiary has received an implanted device that is replaced without cost to the provider or the beneficiary, or where the provider receives full credit for the cost of a replaced device, the amount of reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under § 419.66. Additionally, we are revising our regulation at § 419.45(b)(2) to state that, for situations in which the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the replacement device being implanted, the amount of the reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional-pass through status under § 419.66. The revisions to § 419.45(b)(1) and (2) appear in section XXVII. of this proposed rule.

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was $21,302, and the median cost was $19,521. The final CY 2018 payment rate (calculated using the median cost) was $17,560.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58951), for CY 2019, we continued with our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For more information on the specific policy for assignment of low-volume device-intensive procedures for CY 2019, we refer readers to section III.D.13. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58917 through 58918).

For CY 2020, we finalized our policy to continue establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. In CY 2020, this policy applied to CPT code 0308T which we assigned to APC 5495 (Level 5 Intraocular Procedures) in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61301).

For CY 2021, we propose to continue our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. For CY 2021, this policy would not apply to any procedure. As discussed in section, III.D.3., we received no claims data with CPT code 0308T for this OPPS/ASC proposed rule, which we previously assigned as a low-volume device-intensive procedure for CY 2017 through CY 2020. As such, we propose to assign 0308T a payment weight based on the most recently

available data, from the CY 2020 OPPS final rule, and therefore propose to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Additionally, in the absence of CY 2019 claims data for this CY 2021 OPPS/ASC proposed rule, we propose to use the most recently available data, from the CY 2020 OPPS final rule, to establish the device offset percentage for 0308T. Therefore, the proposed CY 2021 device offset percentage for CPT code 0308T is based on the CY 2020 OPPS final rule device offset percentage of 82.21 percent for CPT code 0308T. For more discussion on the APC assignment and payment rate for CPT code 0308T, see section III.D.3. of this proposed rule.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout the proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in the proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2021 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is described on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Three-Year Transitional Pass-Through Payment Period for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2020

There are 28 drugs and biologicals whose pass-through payment status will expire during CY 2020 as listed in Table 21. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2017 through December 31, 2020. However, there are two groups of drugs and biologicals included in Table

21 whose current period of OPPS pass-through payment is less than 3 years. The first group are five drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status was extended for an additional 2 years from October 1, 2018 until September 30, 2020 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141). The drugs covered by this provision include: HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); HCPCS code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml); HCPCS code Q4195 (Puraply, per square centimeter); HCPCS code Q4196 (Puraply am, per square centimeter); and HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microspheres, per ml). The second group are two diagnostic radiopharmaceuticals, HCPCS code Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and HCPCS code Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries) whose pass-through payment status was extended for an additional 9 months from January 1, 2020 to September 30, 2020 under Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020, which amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(J) to the Act.

In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $130 for CY 2021), as discussed further in section V.B.2. of this proposed rule. We proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2021, as discussed further in section V.B.3. of this proposed rule).

The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of this proposed rule (which is available via the internet on the CMS website).

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TABLE 21: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2020 AND DECEMBER 31, 2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020
J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	03/31/2020
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018	03/31/2020
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324	10/01/2018	09/30/2020
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
Q4195	Puraply, per square centimeter	G	9175	01/01/2019	09/30/2020
Q4196	Puraply am, per square centimeter	G	9176	01/01/2019	09/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2020	09/30/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2020	09/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020

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4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2021

We propose to end pass-through payment status in CY 2021 for 26 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2018 and January 1, 2019, are listed in Table 22. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2021, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6. of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose to have pass-through payment status expire between March 31, 2021 and December 31, 2021 are shown in Table 22.

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TABLE 22: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	03/31/2021
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021
Q2042	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7170	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

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5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2021

We propose to continue pass-through payment status in CY 2021 for 46 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status beginning between April 1, 2019 and April 1, 2020 are listed in Table 23. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2021, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as

supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose to have pass-through payment status expire after December 31, 2021 are shown in Table 23.

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TABLE 23: PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	C9054	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	C9055	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9342	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9344	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, Trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	C9059	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	C9061	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023

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6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulations at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from

the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2021, as we did in CY 2020, we propose to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 24.

TABLE 24: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2021

CY 2021 APC	CY 2021 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We propose to continue to post annually on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $130 for CY 2020 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2021 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2021 and rounded the resulting dollar amount ($130.95) to the nearest $5 increment, which yielded a figure of $130. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary. For this CY 2021 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2021 of $130.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2021 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic

radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed before January 1, 2020 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2021: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2021, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we propose for separately payable drugs and biologicals (other than 340B drugs) for CY 2021, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2021 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2019 (data that were used for payment purposes in the physician's office setting, effective April 1, 2020) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2021, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2019 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2020. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2019 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2020 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2021.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2021 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2019, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2020, along with updated hospital claims data from CY 2019. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this CY 2021 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the second quarter of CY 2020. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2020. These payment rates would then be updated in the January 2021 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2021. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2019 claims data and update cost report information available for the CY 2021 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2021 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2020. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2021, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would continue to receive separate payment in CY 2021.
- HCPCS codes for drugs and biologicals that were packaged in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would remain packaged in CY 2021.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2021 but that then have per-day costs greater than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would receive separate payment in CY 2021.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and

radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2021.

For CY 2021, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2019 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2021 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2019 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2021 is displayed in Table 25.

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TABLE 25: PROPOSED HCPCS CODES TO WHICH THE CY 2021 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug

for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[64]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2021 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2020.

b. Proposed CY 2021 Payment Policy

For CY 2021, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a net rate of ASP minus 28.7 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). In the CY 2020 OPPS/ASC final rule with comment period, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318). For CY 2021, we propose to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We propose that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a net rate of WAC minus 28.7 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We propose that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule

[64] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

(available via the internet on the CMS website), which illustrate the proposed CY 2021 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2020, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for the proposed rule. In general, these published payment rates are not the same as the actual January 2021 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2021 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2020 (July 1, 2020 through September 30, 2020) will be used to set the payment rates that are released for the quarter beginning in January 2021 near the end of December 2020. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2020 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2021, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the proposed rule (reflecting April 2020 ASP data) that do not have ASP information available for the quarter beginning in January 2021. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2021 payment purposes and are only illustrative of the CY 2021 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products is based on the policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we explained that we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For CY 2021, we propose to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also propose to continue our current policy for paying for nonpass-through biosimilars acquired under the 340B program, except that we propose to pay for these biosimilars at the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 28.7 percent of the reference

product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. ASP minus 28.7 percent reflects the proposed net payment rate.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2021, we propose to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2021. Therefore, we propose for CY 2021 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also propose to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2021 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2020, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (83 FR 58979). That is, for CY 2020, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2020 updated furnishing fee was $0.226 per unit.

For CY 2021, we propose to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we propose to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We propose to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2021, we propose to continue to use the same payment policy as in CY 2020 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2021 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the internet on the CMS website.

6. CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Section Overview

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. This payment is governed by section 1847A of the Act, which generally sets a default rate of average sales price (ASP) plus 6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. Although HHS disagrees with that ruling and appealed the decision, HHS meanwhile gathered the relevant survey data from 340B hospitals. As described in detail below, those survey data confirm that the ASP minus 22.5 percent rate is generous to 340B hospitals, and the survey data supports

an even lower payment rate. The following sections expand upon the points discussed in this overview.

Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as ''drugs'') acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not paid under the OPPS and therefore, are not subject to the OPPS payment policy for 340B-acquired drugs. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifiers ''JG'' and ''TB''.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 for CY 2019 and adopted a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321) we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[65] In that same decision, the district court recognized the '' 'havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[66] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[67] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [68] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [69] *Id.* at 19. ''And because

[65] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[66] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[67] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[68] *Id.* at 13.

[69] *Id.* at 19.

HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [70]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the D.C. Circuit, and on July 31, 2020 the court entered an opinion reversing the district court's judgement in this matter. Nonetheless, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters within CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling is upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[71] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion.

We noted that under current law, any changes to the OPPS must be budget neutral, and reversal of the payment adjustment for 340B drugs, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are paid for outpatient items and services covered under the OPPS. In addition, we stated that any remedy that increases payments to 340B hospitals could significantly affect beneficiary cost-sharing. The items and services that could be affected by the remedy were provided to millions of Medicare beneficiaries, who, by law, are required to pay cost-sharing for most items and services, which is usually 20 percent of the total Medicare payment rate. Accordingly, we solicited comments on how to formulate an appropriate remedy in the event of an unfavorable decision on appeal. Those comments are summarized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61323 through 61327).

b. Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs (SCODs)

As discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61326), we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for the fourth quarter of CY 2018 and the first quarter of CY 2019. We noted that the survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years in the event of an adverse decision on appeal in the pending litigation. We explained that our current policy to adjust payment for drugs acquired under the 340B program was the subject of litigation and while we believed we would prevail on appeal, we also believed it was prudent to use the Secretary's existing authority to collect survey data to set OPPS payment rates for drugs acquired under the 340B Program at rates based on hospitals' costs to acquire such drugs. We believe it is appropriate for the Medicare program to pay for SCODs purchased under the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs, and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. We stated that this approach will ensure that the Medicare program uses Medicare trust fund dollars prudently, while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD and, not later than April 1, 2005, to furnish data from such surveys to the Secretary for purposes of setting payment rates under the OPPS for SCODs for 2006. The Comptroller General was then required to make recommendations to the Secretary under section 1833(t)(14)(D)(i)(II) of the Act regarding the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii). Clause (ii) of section 1833(t)(14)(D) of the Act provides that the Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14).

In response to the requirements at section 1833(t)(14)(D)(i)(I) and (II) of the Act, the Government Accountability Office (GAO) surveyed hospitals and prepared a report that included its recommendations for the Secretary regarding the frequency and methodology for subsequent surveys.[72] While GAO recognized that collecting accurate and current drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO's 2006 report recommended that CMS conduct a streamlined hospital survey once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS.[73] In response to questions about whether the data undercounted rebates, GAO acknowledged that their data did not include drug rebates or 340B rebates as part of its calculation.[74] In the CY 2006 OPPS final rule, we explained that the data collected by the GAO was ultimately not used to set payment rates, in part because the data did not fully account for rebates from manufacturers or other price concessions or payments from group purchasing organizations made to hospitals (70 FR 68640). Instead, we adopted a policy to pay hospitals at ASP+6 percent because we believed ASP+6 percent was a reasonable level of payment for both the hospital acquisition and pharmacy overhead cost of drugs and biologicals (70 FR 68642).

[70] *Id.* (citing Declaration of Elizabeth Richter).

[71] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

[72] *https://www.gao.gov/new.items/d06372.pdf.*

[73] *Id.* at 18.

[74] *https://www.gao.gov/new.items/d06372.pdf (Appendix I: Purchase Price for Drug SCODs).*

Between 2006 and 2017, we have generally paid for separately payable drugs for which ASP data is available at ASP plus 6 percent. Beginning in 2018, we adopted the current policy to pay for 340B-acquired drugs at ASP − 22.5 percent to better align Medicare payment with acquisition costs for 340B-acquired drugs. The Medicare Payment Advisory Commission (MedPAC) has consistently stated that Medicare should institute policies that improve the program's value to beneficiaries and taxpayers. For example, in its March 2019 Report to the Congress, MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending. MedPAC stated this rapid growth in OPPS specifically, was ''largely driven by the substantial margins for drugs obtained through the 340B Drug Pricing Program.'' [75] While we continue to believe that ASP+6 percent represents a reasonable proxy for Part B drug acquisition costs for most hospitals, we do not believe the same is true for hospitals that acquire Part B drugs under the 340B program since such hospitals are able to purchase drugs at deeply discounted 340B ceiling prices or at even lower ''sub-ceiling'' prices. For this reason, we concluded that it was appropriate to survey 340B hospitals to gather drug acquisition cost data for drugs acquired under the 340B program to allow us to pay hospitals for these drugs at amounts that approximate the hospitals' acquisition costs.

Population of Surveyed Hospitals

Because of our longstanding belief that ASP plus 6 percent is a reasonable proxy for hospital acquisition costs and overhead for separately payable drugs, we did not believe it was necessary or appropriate to burden hospitals that are not eligible to acquire drugs under the 340B program with a drug acquisition cost survey where we have a proxy for hospital acquisition costs for those drugs. ASP data does not, however, include 340B drug prices. (CY 2011 OPPS/ASC final rule with comment period (75 FR 71800, 71960)). When GAO surveyed hospitals in 2005, it found that the survey ''created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector,'' and recommended that CMS survey hospitals only once or twice per decade to ''occasionally validat[e] CMS's proxy for SCODs' average acquisition costs—the [ASP] data that manufacturers report.'' GAO Report to Congress: *Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS,* 4 (April 2006). Section 1833(t)(14)(D)(ii) requires the Secretary, in conducting periodic subsequent surveys, to take into account GAO's recommendations on the frequency and methodology of subsequent surveys. We considered GAO's conclusion that the 2005 survey created ''considerable burden'' for hospitals and, thus, only surveyed 340B hospitals given our belief that the current payment rate for non-340B hospitals continues to be an appropriate rate. For the same reason, we also limited the data we requested from 340B hospitals to acquisition costs for 340B-acquired drugs, rather than for drugs purchased outside the 340B program for 340B participating hospitals. We note that section 1833(t)(14)(D)(ii) refers to use of surveys conducted by the Secretary to determine the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A). Therefore, we believe it is appropriate to read the two provisions together that permit the Secretary to survey 340B hospitals only and formulate a 340B payment policy for this hospital group that is distinct from the payment policy for non-340B hospitals.

Survey Methodology

Under the authority at section 1833(t)(14)(D)(ii) to conduct periodic subsequent surveys to determine hospital acquisition costs, we administered the survey to 1,422 340B entities between April 24 and May 15, 2020. We requested that all hospitals that participated in the 340B program, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment), supply their average acquisition cost for each SCOD purchased under the 340B program during in the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or first quarter of 2019 (January 1, 2019 through March 31, 2019), which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect any 340B hospital to have acquisition costs for any acquired drug that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or submitted in response to the survey, we stated that we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost in order to produce the most conservative drug discount for when data was missing or not submitted.

We incorporated valuable input from stakeholders on the development and construction of the 340B acquisition cost survey. We collected the stakeholders' input in two rounds of public comment through the survey Paperwork Reduction Act (PRA) submission process. We published the initial 340B drug hospital acquisition cost survey proposal in the **Federal Register** (84 FR 51590) for a 60-day public comment period that began September 30, 2019 and ended November 29, 2019. After incorporating comments from the 60-day public comment period, we released a revised 340B acquisition cost survey proposal in the **Federal Register** (85 FR 7306) for a 30-day public comment period from February 7, 2020 to March 9, 2020.

After incorporating the stakeholders' comments and suggestions from the second public comment period, OMB approved CMS' survey design (OMB control number 0938–1374, expires 10/31/2021), and CMS released the 340B acquisition cost survey to the relevant 340B hospitals under the OPPS. As mentioned earlier in this section, the survey was open from April 24, 2020, to May 15, 2020. The survey sample was 100 percent of the potential respondent universe, or all hospitals that acquired drugs under the 340B Program and were paid for those drugs under OPPS in the fourth quarter of 2018 and/or the first quarter of 2019. We provided respondents with two options to complete the survey: the Detailed Survey and the Quick Survey.

Respondents that selected the Detailed Survey provided acquisition costs for each individual SCOD. We requested that these respondents report the net acquisition cost for each SCOD that they acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts). We stated that if the acquisition cost for the SCOD was unknown, the respondent may leave the field blank and we would use the 340B ceiling price as a proxy for the acquisition cost for that drug. In the survey instructions, we stated that acquisition cost for purposes of the survey meant the price that the hospitals paid upon receiving the product, including, but not limited to,

[75] *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.*

prices paid for 340B drugs purchased via a replenishment model under the 340B program, or under penny pricing. We explained that applicable discounts are any discounts below the discounted ceiling price. We also made clear that for purposes of the survey the 340B drug acquisition cost should be reported regardless of whether the drug was dispensed at all, or whether the drug was dispensed in multiple settings. We only requested the acquisition cost of the drugs acquired under the 340B program during the specified timeframes: the fourth quarter of 2018 and/or the first quarter of 2019. We also stated that acquisition costs for drugs acquired by 340B hospitals outside of the 340B program should not be submitted in response to the survey.

The Quick Survey option allowed the hospital to indicate that it preferred that CMS utilize the 340B ceiling prices obtained from (HRSA) as reflective of their hospital acquisition costs. Additionally, we stated that in instances where the acquisition price for a particular drug is not available or submitted in response to the survey, we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost because the price for a drug acquired under the 340B program cannot be higher than the 340B ceiling price by statute. Finally, we noted that where a hospital did not affirmatively respond to the Detailed or Quick Survey within the open period of response, we would use the 340B ceiling prices in lieu of their responses because the ceiling price represents the highest possible price that a 340B hospital could permissibly be required to pay for a 340B-acquired drug.

c. Analysis of Hospital Acquisition Cost Survey Data for 340B Drugs

The results of the survey, which closed on May 15, 2020 are as follows: Seven percent (n=100) of surveyed hospitals affirmatively responded via the Detailed Survey option; 55 percent (n=780) of surveyed hospitals affirmatively responded via the Quick Survey option; and the remaining 38 percent (n=542) of surveyed hospitals did not respond affirmatively to either survey option. As previously noted, we applied 340B ceiling prices for hospitals that did not affirmatively respond to the survey; such action may skew the survey results towards the *minimum* average discount (that is, the ceiling price) that a 340B hospital would receive on a drug.

We also examined the hospital characteristics of those hospitals that submitted either a Detailed or Quick Survey to the general 340B survey population. The characteristics we analyzed included hospital bed count, teaching hospital status, hospital type, and geographic classification as a rural or urban hospital. Our findings showed that the survey respondent hospitals were generally similar to the general 340B survey population.

d. Proposed Payment Policy for Drugs Acquired Under the 340B Program for CY 2021 and Subsequent Years

(1) Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). In this proposed rule, we are exercising the authority to vary the amount of payment for the group of hospitals that is enrolled in the 340B program because their drug acquisition costs vary significantly from those not enrolled in that program. Section 1833(t)(14)(A)(iii) of the Act allows the Secretary to exercise discretion to vary payment by hospital group, ''as defined by the Secretary based on the volume of covered OPD services or other relevant characteristics.'' We believe that is it within the Secretary's authority to distinguish between hospital groups based on whether or not they are covered entities under section 340B(a)(4) of the PHSA that are eligible to receive drugs and biologicals at discounted rates under the 340B program. We believe that the significant drug acquisition cost discounts that 340B covered entity hospitals receive enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we propose to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I).

(2) Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug ''as determined by the Secretary taking into account'' the survey data collected under subparagraph (D). We interpret the reference to acquisition costs being ''determined'' by the Secretary, ''taking into account'' survey data, to give us discretion to determine the appropriate payment rate based on data collected from the hospital acquisition cost survey for 340B drugs. We propose to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. We note that 340B ceiling prices are protected from disclosure both because the prices themselves are sensitive, and because they could potentially be used to reverse-engineer average manufacturer prices, which are protected under section 1927(b)(3)(D). We also pledged confidentiality of individual responses regarding acquisition prices for each SCOD to the extent required by law. Given that the survey data is heavily weighted towards 340B ceiling prices (because 340B ceiling prices were used for any SCODs within the Detailed Survey for which a hospital did not provide responses, for hospitals that selected the Quick Survey option, and for hospitals that did not affirmatively respond) and since ceiling prices are protected by law from public disclosure, we are instead proposing to establish one aggregate discount amount relative to ASP for SCODs acquired under the 340B program rather than proposing drug-specific prices, which could reveal sensitive or protected pricing information.

(3) Methodology To Calculate ASP Reduction Amount Based on Survey Data

As described in detail in the following sections, we analyzed the survey results and applied various statistical methodologies to determine an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs and biologicals. In fairness to hospitals, we generally chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals. This includes the use of 340B ceiling prices, which must be kept confidential, where applicable in the survey results. Based on our analysis of the available information, we estimate that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP minus 34.7 percent.

We determined the average discount of 34.7 percent by assessing a number of factors including: Multiple measures of central tendencies (arithmetic mean,

median, geometric mean); the effect of including penny priced drugs; mapping of multi-source NDCs to a single HCPCS code; weighting values by volume/utilization; and applying trimming methodologies to remove anomalous or outlier data. The analysis of each of these variables is discussed in the next section.

(a) Selecting an Averaging Methodology

When determining the appropriate average reduction amount relative to ASP for 340B drugs, we assessed multiple measures of central tendencies, including the arithmetic mean, median, and geometric mean, on the typical 340B discount based on drug acquisition cost survey data. Based upon the cumulative data from the Detailed Survey option, the Quick Survey option, and imputed responses for hospitals that did not affirmatively respond, we analyzed the effects of each averaging method, combining the data from all three sources in both survey quarters (fourth quarter 2018 and first quarter 2019). Using the raw data without accounting for outliers, we determined that the arithmetic mean would result in an average discount from ASP of approximately 66.3 percent; the median would result in an average discount from ASP of approximately 70.4 percent, and the geometric mean would result in an average discount from ASP of approximately 58.3 percent.

Under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. Minimizing outliers is consistent with our methodology to estimate an average or typical 340B discount that is representative across all 340B SCODs. Therefore, we propose to utilize the geometric mean discount to ASP from both survey quarters—2018 Q4 and 2019 Q1—as a component of our overall analysis of the survey data. Without any further adjustments, applying the geometric mean to the survey results would result in an average drug acquisition cost estimate of ASP minus 58.3 percent for 340B acquired drugs.

(b) Volume Weighting Survey Data

While we realize the geometric mean minimizes the effects of some outliers, it does not take into consideration several other important factors. Notably, we believe that in calculating the average discount that 340B drugs receive relative to ASP, we should take into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019, to give a better reflection of each drug's overall utilization under the OPPS. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. That is, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. We incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. Specifically, we calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than that of a drug for snake anti-venom that has a relative low utilization in the OPPS. The data for CY 2018 Q4 was volume weighted based upon OPPS utilization during CY 2018 as determined using OPPS claims data. The data for CY 2019 Q1 was volume weighted based upon OPPS utilization during CY 2019 as determined using OPPS claims data. This resulted in a change in the geometric mean to an average discount of 58.0 percent from 58.3 percent non-weighted.

(c) Addressing HCPCS Code With Multiple NDCs

In addition, a small portion of the SCODs that were subject to the 340B drug acquisition cost survey contain multiple NDCs that map to a single HCPCS code. This is because these drugs are multiple source drugs, meaning that they were manufactured by different entities and have varying package sizes or strengths, and thus, multiple different NDCs for the same drug. For payment purposes under the OPPS, we pay for drug products based on the drug's HCPCS code, regardless of which NDC is used. Hospitals that completed the Detailed Survey option were instructed to report their average acquisition costs for each drug during the surveyed quarters per HCPCS code. However, for those hospitals that opted for the Quick Survey option or that did not affirmatively respond, we were unable to determine which combination of NDCs mapped to the HCPCS codes these entities would have used during the given quarters. Therefore, we analyzed the effects of averaging all of the NDCs' acquisition costs for a given HCPCS when determining the average discount, as well as selecting the NDC with the highest acquisition cost for a given HCPCS code and using that NDC's acquisition cost amount to determine the average discount. When we calculate the average discount using an average of the acquisition costs for all of the NDCs assigned to the HCPCS code, the average volume weighted geometric mean discount off of ASP is 58.0 percent. The 58.0 percent was calculated by taking all of the various NDCs (across various manufacturers, package sizes, and strengths) for the same drug and averaging the unit costs together in order to arrive at a single amount for each HCPCS code for a drug. When we calculated the average discount using the highest acquisition cost NDC for each HCPCS code for a drug, the average volume weighted geometric mean discount from ASP is 47.0 percent. This was achieved by analyzing all of the various NDCs (across various manufacturers, package sizes, and strengths) assigned to the HCPCS code for the same drug and selecting the NDC that has the highest unit cost in order to arrive at a single cost for each HCPCS code. Consistent with the general principle of choosing the methodological approach that is most generous to hospitals, we propose to use the highest acquisition cost NDC for each HCPCS code for a drug to determine the average 340B discount.

(d) Addressing Penny Pricing in the Survey Data

As part of our analysis of the survey data, we examined the effect of including ''penny priced'' drugs on the average discount off of ASP. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).[76] The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA. Penny pricing occurs when, under section 1927(c)(2)(A) of the Social Security Act, the AMP increases at a rate faster than inflation, in which case the manufacturer is required to pay an additional rebate amount, which is reflected in an increased URA and could result in a 340B ceiling price of zero. We propose to exclude penny priced drugs to remove outliers that may distort the average discount in order to provide the most conservative estimate of the average 340B discount from ASP. HRSA noted in the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Final Rule (82 FR 1210) that although infrequent, that there are instances when the 340B ceiling price is zero. HRSA did not believe that it is consistent with the statutory scheme to

[76] *https://www.hrsa.gov/opa/updates/2015/may.html.*

set the price at zero. In this circumstance, HRSA required that manufacturers charge a $0.01 for the drug, which they believed best effectuates the statutory scheme by requiring a payment.[77]

We acknowledge that penny pricing of drugs is not intended to be permanent and, by its very nature, is dynamic, meaning the select group of drugs to which penny pricing applies could vary from quarter to quarter. We analyzed the inclusion and exclusion of penny pricing on the overall average discount of 340B drugs compared to ASP. As expected, we found that the excluding penny pricing provides a much more conservative estimate of the average 340B discount from ASP relative to including penny pricing. When we excluded penny pricing, the geometric mean volume weighted average discount, using the highest NDC for a drug's HCPCS code, decreased to 40.9 percent from 47.0 percent. We observed penny pricing in less than 10 percent of the drugs surveyed. Because penny pricing is dynamic and the drugs to which it applies may vary from quarter to quarter, we believe it is appropriate to propose to exclude penny pricing from our survey analysis, although we acknowledge that penny pricing, when it does apply, represents the acquisition cost for the drug to which it applies.

We are concerned that including a discount of a penny priced drug from the two quarters surveyed may inappropriately increase the average discount, where the drug may not have been priced based on penny pricing in following or preceding quarters. However, it also is the case that a drug could have penny pricing for any given quarter and it could be appropriate to include penny priced drugs in the calculation of the average acquisition cost because in such cases, penny prices do represent the maximum (ceiling) price the 340B hospital would pay for that drug. Nonetheless, in order to provide for a more conservative discount estimate, we propose to exclude penny priced drugs at this time from our analysis, but we welcome public comment on whether such policy accurately represents 340B-drug acquisition costs.

(e) Addressing Outliers

In response to the Detailed Survey, hospitals provided some drug acquisition cost data that exceeded 340B ceiling prices, and in some cases even exceeded the ASP or ASP+6 percent payment rate for certain drugs. As previously noted, covered entities cannot be required to pay more than the ceiling price to acquire a drug under the 340B program. Therefore, we attributed any Detailed Survey acquisition cost data greater than the ceiling price to potential data entry error, for instance, miscalculation or incorrect decimal point placement. However, because hospitals may have been overcharged for their drug acquisition costs and could have accurately reported acquisition costs greater than the HRSA ceiling price, we did not eliminate these data from our calculations. Instead, consistent with our standard methodology for processing extreme outliers under the OPPS, we excluded responses for any SCODs that were three standard deviations from the geometric mean. We believe applying a three standard deviation limit to the reported acquisition data is appropriate because it removes outliers from both the high and low reported values. In addition, applying a three standard deviations limit may be more representative of the respondents' acquisition cost, even though it may not eliminate some data values that are above the ceiling price. While this approach means that some values above the ceiling price will be included in our data analysis, we are not proposing to trim them because we propose to apply a standard trimming methodology. The cumulative application of this trimming methodology, along with other methodologies applied to the survey data described above, results in an average acquisition cost for drugs that hospitals acquire under the 340B program of ASP minus 34.7 percent. For the reasons previously discussed, we propose to exclude survey data from the Detailed Survey that is more than three standard deviations from the mean. We note that we also explored capping any survey submissions received at the 340B ceiling price, as no covered entity can be required to pay more than the ceiling price. This approach, holding all other methodological approaches constant, would have resulted in an average acquisition cost of ASP minus 41.5 percent for drugs acquired under the 340B program.

Table 26, Aggregate 340B Drug Program Cost Savings Percentage Relative to ASP, shows the aggregate 340B drug program discount percentage relative to ASP using several different statistical measures. In this table, we outlined some additional figures following a similar path as described above. For example, we arrived at the 33.8 percent figure in the table under median, and penny pricing excluded, by initially choosing the median as the averaging methodology, and then performing trimming methodologies as described above, which include volume weighting by HCPCS, using the highest NDC per HCPCS, and using only data within three standard deviations of the median. This would have resulted in a final proposed discount of 33.8 percent. While this final discount appears more generous to hospitals than our proposal, we do not believe it is appropriate. Specifically, we believe using the geometric mean as outlined in the methodology above is the most generous methodology for establishing a final discount amount that also maintains accuracy and consistency with past OPPS practices. As described previously, under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. As an additional example, under the arithmetic mean methodology with penny pricing included in table 26, the final determined discount was determined to be 23.1 percent. We arrived at this figure of 23.1 percent by initially choosing the arithmetic mean as the averaging methodology, and then performing trimming methodologies as described above, with the exception of including penny prices in this figure. Similar to the discussion above regarding the use of the median, we do not think utilizing the arithmetic mean is appropriate or consistent with the averaging methodologies historically used under the OPPS. The arithmetic mean could easily skew towards outlier data and anomalous data not captured by previously described trimming methodologies. Additionally, with this 23.1 percent figure, while penny pricing is a valid maximum (*i.e.,* ceiling) price for drugs to which it applies, as noted above we believe it would be appropriate to exclude penny priced drugs for purposes of our proposal.

We believe the manner in which we arrived at the proposed payment amount of ASP minus 34.7 percent for 340B-acquired drugs is the most appropriate and accurate method of determining the average discount or typical discount. We believe it is reflective of stakeholder's actual acquisition costs, and is as generous as possible without compromising accuracy. We also believe the geometric mean is the most appropriate averaging methodology as it mitigates the effects of outliers relative to the arithmetic mean and median and is consistent with OPPS payment methodologies. Although ceiling prices are protected by

[77] *https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf.*

statute and the respondents to the survey were given a pledge of confidentiality, we are exploring and seek comment on the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency.

Table 26: AGGREGATE 340B DRUG PROGRAM COST SAVINGS PERCENTAGE RELATIVE TO ASP*

	Weighted by HCPCS Volume, Highest NDC per HCPCS used, and only Data with 3 Standard Deviations of the Mean					
	With Penny Pricing Included			With Penny Pricing Excluded		
	Arithmetic Mean	Median	Geometric Mean	Arithmetic Mean	Median	Geometric Mean
Average 2018Q4-2019Q1	23.1%	39.6%	39.4%	20.3%	33.8%	34.7%

* Based on Combined Survey Data.

(4) Determining an Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs typically also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs.

In the MedPAC report from 2005,[78] MedPAC recommended that the Secretary:

- Establish separate, budget neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals;
- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

Because we took a conservative approach in estimating the average acquisition costs for 340B-acquired drugs, we do not believe that it is imperative to establish an add-on for overhead and handling as we believe that such a conservative estimate may already account for the costs of overhead and handling. In addition, our current 340B drug payment policy under the OPPS pays separately payable drugs at ASP minus 22.5 percent with no add-on payment because this payment rate represents the minimum average discount that a 340B entity would receive on a drug. We believe hospitals receive a significant margin on 340B drugs under our current policy, so an additional add-on payment is not necessary. Nonetheless, under the methodology in section 1847A, the Part B payments for separately payable drugs and biologicals furnished by practitioners and certain suppliers generally include an add-on set at 6 percent of the ASP for the specific drug. As discussed in the CY 2019 Physician Fee Schedule final rule with comment period (83 FR 59661–59662) the 6 percent add-on is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. We realize that the acquisition costs for drugs acquired under the 340B program are significantly lower than for those drugs purchased outside of the 340B program, so we did not find it appropriate to base the add-on for 340B drugs on the 340B acquisition cost as previously discussed. However, we believe that it is reasonable to assume that a given drug will have similar overhead and other administrative costs regardless of whether the drug was purchased under the 340B Program or a by non-340B entity. Additionally, utilizing a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs outside of the 340B program.

Therefore, for CY 2021 and subsequent years, we propose to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent. Under this payment methodology, each drug would receive the same add-on payment regardless of whether it is paid at the 340B rate or at the traditional ASP rate for drugs not purchased under the 340B program. We note that this add-on percentage would be more generous to hospitals than adding 6 percent of the reduced 340B rate. As an example, assuming a non-340B drug is paid its ASP of $1,000 and $60 for the 6 percent add-on, the 340B rate would be $653 ($1,000 − $347) plus $60 or $713 total, instead of $653 plus $39.18 (6 percent of the reduced rate of $653) which would equal $39.18 or $692.18 total. We propose that this payment methodology would be our Medicare payment policy for 340B-acquired drugs going forward for CY 2021 and subsequent years.

(5) 340B Payment Policy for Drugs for Which ASP Is Unavailable

As we clarified in the CY 2019 OPPS/ASC proposed rule, the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. We propose the 340B payment adjustment for WAC-priced drugs mirror that of ASP payment with

[78] *http://medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

payment being WAC minus 34.7 percent plus 6 percent of the drug's WAC, except for when WAC plus 3 percent policy applies under 1847A(c)(4) and as discussed in V.B.2.b., for which we would propose a payment rate of WAC minus 34.7 percent plus 3 percent of the drug's WAC. Previously, AWP-priced drugs have had a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. Similarly, for CY 2021, we propose to pay for drugs paid at AWP under the 340B program at 95 percent AWP first reduced by 6 percent to generate a value that is similar to ASP or WAC with no percentage mark up. Then we propose to apply the net 28.7 percent reduction resulting in a payment rate of 63.90 percent of AWP.

(6) 340B Payment Policy Exemptions

In the CY 2018 OPPS/ASC proposed rule, we sought public comment on whether, due to access to care issues, certain groups of hospitals, such as those with special adjustments under the OPPS (for example, children's hospital or PPS-exempt cancer hospitals) should be excepted from a policy to adjust OPPS payments for drugs acquired under the 340B program. Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. Taking into consideration the comments regarding rural hospitals, we believed further study on the effect of the 340B drug payment policy was warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. Accordingly, we believed and continue to believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2021 and subsequent years, similar to previous years, we propose that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be excepted from the 340B payment adjustment and that these hospitals continue to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in future rulemaking.

As discussed in section V.B.2.c. of the CY 2019 OPPS/ASC proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. Similarly, for CY 2021, we propose to pay nonpass-through biosimilars acquired under the 340B Program at the biosimlar's ASP minus the net payment discount reduction, 34.7 percent plus an add on of 6 percent, of the biosimilar's ASP, for a net payment rate of the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP.

e. Alternative Proposal To Continue Policy To Pay ASP − 22.5 Percent

Previously, we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchased drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, this proposed policy would continue the current Medicare payment policy for CY 2021 and subsequent years.

Summary

In summary, we propose for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent using the authority under section 1833(t)(14)(A)(iii)(I) of the Act. This proposal includes our previously discussed methodology used to arrive at the 34.7 percent average discount that we propose to apply to all drugs acquired under the 340B program. This methodology includes using the geometric mean of the survey data, volume weighting the average based upon utilization of the drug in the OPPS, using the highest priced NDC when multiple NDCs are available for a single HCPCS code, eliminating penny pricing from the average, and eliminating any data outside of 3 standard deviations from the mean when calculating the average discount of 34.7 percent. Our intent is that, if finalized, this payment methodology would apply begin January 1, 2021 and any changes to this permanent payment policy would be required to be adopted through notice and comment rulemaking. We are also proposing that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B

payment policy for CY 2021 and subsequent years. Finally, we note that we propose in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs as we prevailed on appeal to the D.C. Circuit in the litigation.

7. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277); APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277); or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273). In CY 2020, the payment rate for APC 5053 (Level 3 Skin Procedures) was $497.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,622.74, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,766.13. This information also is available in Addenda A and B of the CY 2020 OPPS/ASC final rule with comment period, correction notice (which is available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2021. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (84 FR 61327 through 61328).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: Establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinement to the existing policies are consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking. We received many responses to our request for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the

existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products.

b. Discussion of CY 2019 and CY 2020 Comment Solicitations for Episode-Based Payment for Graft Skin Substitute Procedures

The methodology that commenters discussed most in response to our comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings we have had with the wound care community has been a lump-sum ''episode-based'' payment for a wound care episode. Commenters that supported an episode-based payment believe that it would allow health care professionals to choose the best skin substitute to treat a patient's wound and would give providers flexibility with the treatments they administer. These commenters also believe an episode-based payment helps to reduce incentives for providers to use excessive applications of skin substitute products or use higher cost products to generate more payment for the services they furnish. In addition, they believe that episode-based payment could help with innovations with skin substitutes by encouraging the development of products that require fewer applications. These commenters noted that episode-based payment would make wound care payment more predictable for hospitals and provide incentives to manage the cost of care that they furnish. Finally, commenters for an episode-based payment believe that workable quality metrics can be developed to monitor the quality of care administered under the payment methodology and limit excessive applications of skin substitutes.

However, many commenters opposed establishing an episode-based payment. One of the main concerns of commenters who opposed episode-based payment was that wound care is too complex and variable to be covered through such a payment methodology. These commenters stated that every patient and every wound is different; therefore, it would be very challenging to establish a standard episode length for coverage. They noted that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment, given the diversity of patients receiving wound care and their providers who administer treatment, as well as the variety of pathologies covered in treatment. Also, these commenters questioned how episodes would be defined for patients when they are having multiple wounds treated at one time or have another wound develop while the original wound was receiving treatment. These commenters expressed concerns that episode-based payment would be burdensome both operationally and administratively for providers. They believe that CMS will need to create a large number of new APCs and HCPCS codes to account for all of the patient situations that would be covered with an episode-based payment, which would increase burdens on providers. Finally, these commenters had concerns about the impacts of episode-based payment on the usage of higher cost skin substitute products. They believe that a single payment could discourage the use of higher-cost products because of the large variability in the cost of skin substitute products, which could limit innovations for skin substitute products.

The wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy encouraged us to continue to study the issues with episode-based payment. Therefore, we sought further comments from stakeholders and other interested parties regarding skin substitute payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations.

One possible policy construct that we sought comments on was whether to establish a payment period for skin substitute application services (CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278) between 4 weeks and 12 weeks. Under this option, we could also assign CPT codes 15271, 15273, 15275, and 15277, and HCPCS codes C5271, C5273, C5275, and C5277 to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. Our research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments.

Several commenters were in favor of establishing a comprehensive APC with either an option for a complexity adjustment or outlier payments to pay for higher cost skin substitute application procedures. The commenters supported the idea of having a traditional comprehensive APC payment for standard wound care cases with a complexity adjustment or outlier payment to handle complicated or costly cases. However, they also expressed concerns about how many payment levels would be available in the skin substitute procedures APC group since a complexity adjustment can only be used if there is an existing higher-paying APC to which the service receiving the complexity adjustment may be assigned. A couple of commenters wanted more opportunities for services to receive a complexity adjustment through using clusters of procedure codes that reflect the full range of wound care services a beneficiary receives instead of using code pairs to determine if a complexity adjustment should apply. Other commenters suggested that episodic payments be risk-adjusted to account for clinical conditions and co-morbidities of beneficiaries with outlier payments and that complexity adjustments be linked to beneficiaries with more comorbidities.

Some commenters opposed the idea of a complexity adjustment for skin

substitute application procedures. The commenters stated there was not enough detail in the comment solicitation to understand how a complexity adjustment would work with an episodic payment arrangement. Commenters also expressed concerns that payment rates for comprehensive APCs may not be representative of the wound care services that would be paid within those APCs. One commenter stated that payment policy is not the right way to resolve issues with the over-utilization and inappropriate use of skin substitutes because they are concerned that major changes in payment methodology, such as episodic payment, could lead to serious issues with the care beneficiaries receive. In recent meetings, stakeholders have expressed concerns that establishing a comprehensive APC for graft skin substitute procedures could lead to other unrelated wound care services such as hyperbaric oxygen treatments being bundled into those procedures. Some stakeholders have provided suggestions to provide additional payment for the treatment of complicated wounds, similar to a complexity adjustment, without bundling unrelated wound care services.

The additional comments we received in CY 2020 related to including a complexity adjustment with an episode-based payment, along with the comments we received on episode-based payment in general from the CY 2019 comment solicitation show, that there are many issues that continue to require study for this payment methodology. In addition, we also need more time to assess the benefits and drawbacks of episode-based payment as compared to other possible options to change the payment methodology for graft skin substitute procedures. Therefore in CY 2021, we will continue our review of the feasibility of using episode-based payment for graft skin substitute procedures, and we will not propose any episode-based payment for these procedures.

c. Discussion of CY 2019 and CY 2020 Comment Solicitations To Have a Single Payment Category for Graft Skin Substitute Procedures

Another policy option on which we solicited comments in CY 2019 and CY 2020 was to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Under this option, the only available procedure codes to bill for graft skin substitute procedures would be CPT codes 15271 through 15278. HCPCS codes C5271 through C5278 would be eliminated. Providers would bill CPT codes 15271 through 15278 without having to consider either the MUC or PDC of the graft skin substitute product used in the procedure. There would be only one APC for the graft skin substitute application procedures described by CPT codes 15271 (Skin sub graft trnk/arm/leg), 15273 (Skin sub grft t/arm/lg child), 15275 (Skin sub graft face/nk/hf/g), and 15277 (Skn sub grft f/n/hf/g child). The payment rate would be the geometric mean of all graft skin substitute procedures for a given CPT code that are covered through the OPPS. For example, under the current skin substitute payment policy, there are two procedure codes (CPT code 15271 and HCPCS code C5271) that are reported for the procedure described as ''*application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*''.

Commenters and stakeholders who support this option believed it would remove the incentives for manufacturers to develop and providers to use high cost skin substitute products and would lead to the use of lower cost, quality products. Commenters and stakeholders note that lower Medicare payments for graft skin substitute procedures would lead to lower copayments for beneficiaries. In addition, commenters and stakeholders believe a single payment category would reduce incentives to apply skin substitute products in excessive amounts. Commenters and stakeholders also believe a single payment category is clinically justified because they stated that many studies have shown that no one skin substitute product is superior to another. Supporters of a single payment category believed it would simplify coding for providers and reduce administrative burden. Finally, some stakeholders believe that a single payment category policy could serve as a transitional payment policy for graft skin substitute products while we continue to study the feasibility of establishing an episode-based payment for skin substitutes.

Most commenters and stakeholders were opposed to a single payment category for skin substitute products. Commenters and stakeholders stated that the large difference in resource costs between higher cost and lower cost skin substitute products would provide an incentive for hospitals to use the most inexpensive products, which would hurt both product innovation and the quality of care beneficiaries receive. Commenters and stakeholders were concerned that a single payment category would encourage providers to choose financial benefit over clinical efficacy when determining which skin substitute products to use.

These commenters and stakeholders also stated that a single payment category would increase incentives for providers to use cheaper products that require more applications to generate more revenue and emphasize volume over value. A couple of commenters believed that overall Medicare spending on skin substitutes would be higher with a single payment category than under the current payment methodology, which has separate payment for higher cost and lower cost skin substitutes. The reason spending would go up according to the commenters is the overpayment for low cost skin substitutes by Medicare would exceed the savings Medicare would receive on reduced payments for higher cost skin substitutes.

Further, commenters and stakeholders stated that a single payment rate would lead to too much heterogeneity in the products receiving payment through the skin substitute application procedures. That is, the same payment rate would apply to skin substitute products whether they cost less than $10 per cm^2 or over $200 per cm^2 and regardless of the type of wound they treat. Commenters and stakeholders would prefer to have multiple payment categories where the payment rate is more reflective of the cost of the product. Commenters and stakeholders believe that a single payment category would discourage providers from treating more complicated wounds and wounds larger than 100 cm^2.

The responses to the comment solicitation demonstrated the potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare in general. In addition, a single payment category may help to lower administrative burden for providers. Conversely, we are cognizant of other commenters' concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market. Nonetheless, we are persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment.

We believe some of the concerns commenters who oppose a single

payment category for skin substitute products raised might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. Accordingly in CY 2020, we solicited public comments that provide additional information about how commenters believe we should transition from the current low cost/high cost payment methodology to a single payment category.

Such suggestions to facilitate the payment transition from a low cost/high cost payment methodology to a single payment category methodology included—

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

Those commenters in favor of a single payment category did not see a need for a transition period or wanted only a one-year transition period. Conversely, those commenters opposed to a single payment category either who did mention the idea of a transition period or wanted it to last multiple years, with one commenter suggesting a transition period of four years. In the end, having a transition period before establishing a single payment category did not affect the views of commenters who were initially opposed to establishing a single payment category as they continued to be against the policy option.

Based on the comments received regarding establishing a single payment category for graft skin substitute procedures, we need more time to consider the trade-offs between potential benefits of a single category against the potential substantial drawbacks. We also need to consider the merits of this policy option compared to episode-based payment for graft skin substitute procedures. Therefore, we are not proposing a single payment category for graft skin substitute procedures for CY 2021.

d. Proposals for Packaged Skin Substitutes for CY 2021

For CY 2021, consistent with our policy since CY 2016, we propose to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 through CY 2018 final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2021 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed CY 2021 PDC threshold is $936 (rounded to the nearest $1). We also propose to clarify that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products as described in section V.B.7.d. of this proposed rule. We also want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2021, as we did for CY 2020, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we propose to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2021, we propose that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2021, we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2021 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). Table 27 displays the final CY 2021 cost category assignment for each skin substitute product.

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TABLE 27: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2021

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
C9363	Integra meshed bil wound mat	High	High*
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High*
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	Low	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	High
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	Low	High
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	Low	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	Low	Low
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Proposed CY 2021 High/Low Cost Assignment
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	Low
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	Low	High
Q4227	Amniocore per sq cm	Low	Low
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	Low
Q4234	Xcellerate, per sq cm	Low	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	Low	Low
Q4238	Derm-maxx, per sq cm	Low	Low
Q4239	Amnio-maxx or lite per sq cm	Low	Low
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2021, but are assigned to the high cost group because they were assigned to the high cost group in CY 2020.

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e. Proposal To Allow Synthetic Skin Graft Sheet Products To Be Reported With Graft Skin Substitute Procedure Codes

The CY 2014 OPPS/ASC final rule with comment period describes skin substitute products as ''. . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . . [T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue.'' (78 FR 74930 through 74931) The CY 2014 final rule also described skin substitutes as ''. . . a class of products that we treat as biologicals . . .'' and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).

The 2014 rule did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products. Then in 2018, a manufacturer made a request that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes, including CPT codes 15271 through 15278 and C5271 through C5278 starting in 2019. Initially, the synthetic product was not described as a graft skin substitute product. However, we now believe that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes.

This view is supported by a paper referenced in a report we cited in the CY 2014 OPPS/ASC final rule with comment period titled ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'', which is available on the AHRQ website at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf*. That paper, titled ''Regenerative medicine in dermatology: Biomaterials, tissue engineering, stem cells, gene transfer and beyond'' by Dieckmann et al.,[79] states that skin substitutes should be divided into two broad categories: Biomaterial and cellular. The paper explains that ''. . . biomaterial skin substitutes do not contain cells (acellular) and are derived from natural or synthetic sources . . .''[80] The paper continues by describing biomaterial skin substitutes further: ''Synthetic sources include various degradable polymers such as polylactide and polyglycolide. Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding

[79] Dieckmann C, Renner R, Milkova L, et al. Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond. Exp Dermatol 2010 Aug;19(8):697–706.

[80] Ibid, Dieckmann C, Renner R, Milkova L, et al.

cells.'' [81] The paper by Dieckmann et al. confirms that skin substitute products may be synthetic products as well as biological products.

Therefore, for CY 2021 we propose to include synthetic products in addition to biological products in our description of skin substitutes. Our new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We also propose to retain the additional description of skin substitute products from the CY 2014 OPPS final rule which states ''. . . that skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue . . .'' (78 FR 74930 through 74931).

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2021 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the proposed CY 2021 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2021 pass-through spending estimate for device categories with pass-through payment status. We based the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2021, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our estimate of drug and biological pass-through payment for CY 2021 for this group of items is $473.4 million, as discussed below, because we propose that most nonpass-through separately payable drugs and biologicals would be paid under the CY 2021 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which are currently generally paid at ASP minus 22.5 percent, but for which we propose to pay a net rate of ASP minus 28.7 percent, and because we proposed to pay for CY 2021 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this CY 2021 OPPS/ASC proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section V.B.1.c. of this CY 2021 OPPS/ASC proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2020. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2021 was not $0, as discussed below. In section V.A.6. of this CY 2021 OPPS/ASC proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we propose to offset the amount of pass-through

[81] Ibid, Dieckmann C, Renner R, Milkova L, et al.

payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the CY 2021 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2021 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

For CY 2021, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2021, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2020 (83 FR 61336 through 61337).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2021, there are four active categories for CY 2021. The active categories are described by HCPCS codes C1734, C1824, C1982, and C2596. Based on the information from the device manufacturer, we estimate that C1824 will cost $46 million in pass-through expenditures in CY 2021, C1982 will cost $116.3 million in pass-through expenditures in CY 2021, C2596 will cost $11.3 million in pass-through expenditures in CY 2021, and C1734 will cost $37.2 million in pass-through expenditures in CY 2021. Therefore, we propose an estimate for the first group of devices of $210.8 million.

In estimating our proposed CY 2021 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2021; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2021; and contingent projections for new device categories established in the second through fourth quarters of CY 2021. For CY 2021, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. The proposed estimate of CY 2021 pass-through spending for this second group of device categories is $99 million.

There are 5 devices we are evaluating for potential pass-through payment status in the CY 2021 rulemaking cycle: Barostim NEO® System, Hemospray® Endoscopic Hemostat, EXALT™ Model D Single-Use Duodenoscope, The SpineJack® Expansion Kit, and Customflex® Artificial Iris. The manufacturers of these systems provided utilization and cost data that indicate the spending for the devices would be approximately $4 million for Barostim NEO® System, $40 million for Hemospray® Endoscopic Hemostat, $40 million for EXALT™ Model D Single-Use Duodenoscope, $14 million for SpineJack® Expansion Kit, and $600 thousand for Customflex® Artificial Iris. Therefore, we are finalizing an estimate of $99 million for this second group of devices for CY 2021.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2021, we propose to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2021 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2021, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we generally currently pay ASP minus 22.5 percent but for which we propose to pay a net rate of ASP minus 28.7 percent. Therefore, the payment rate difference between the pass-through payment amount and the nonpass-through payment amount is $463.4 million for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2021 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2021 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs that will be on pass-through in CY 2021.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2021, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2021 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2021), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2021 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2021 pass-through

payments for this second group of drugs, we calculate a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2021 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2021 would be approximately $783.2 million (approximately $309.8 million for device categories and approximately $473.4 million for drugs and biologicals) which represents 0.934 percent of total projected OPPS payments for CY 2021 (approximately $84 billion). Therefore, we estimate that pass-through spending in CY 2021 will not amount to 2.0 percent of total projected OPPS CY 2021 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2021, we propose to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2020. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). As discussed in section X.D of that proposed rule and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58818 through 59179), CY 2020 was the second year of the 2-year transition of this policy, and beginning in CY 2020, these departments are paid the site-specific PFS rate for the clinic visit service. We note that on September 1, 2019, the United States District Court for the District of Columbia (the district court) entered an order vacating the portion of the CY 2019 OPPS/ASC final rule with comment period that adopted the volume control method for clinic visit services furnished by nonexcepted off-campus PBDs and remanded the matter to the Secretary for further proceedings consistent with the district court's opinion.[82] In the CY 2020 OPPS/ASC final rule with comment period, we acknowledged that the district court vacated the volume control policy for CY 2019 and we stated that we were working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We also stated that we did not believe it was appropriate at that time to make a change to the second year of the 2-year phase-in of the clinic visit policy. We explained that we still had appeal rights, and were evaluating the rulings and considering whether to appeal from the final judgment. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011, (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively

[82] *American Hospital Ass'n, et al.* v. *Azar,* No. 1:18–cv–02841–RMC (D.D.C. Sept. 17, 2019).

on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352). We refer readers to section VIII.D. of this proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30th, 2020 interim final rule with comment (85 FR 27562–27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE.

B. Proposed PHP APC Update for CY 2021

1. Proposed PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2021 and subsequent years, we propose to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $121.62 calculated last year for CY 2020 ratesetting (84 FR 61339 through 61344), as the basis for developing the CY 2021 CMHC APC per diem rate. For CY 2021 and subsequent years, we also propose to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345). Following this methodology, we propose to use the cost floor value of $121.62 for CMHCs as the basis for developing the CY 2021 CMHC APC per diem rate. We propose to use the CY 2021 hospital-based PHP geometric mean per diem cost of $243.94, calculated in accordance with our existing methodology for hospital-based PHPs, as the basis for developing the CY 2021 hospital-based APC per diem rate. We propose to use the most recent updated claims and cost data to determine CY 2021 geometric mean per diem costs in this proposed rule. The rationale behind this proposal is discussed in greater detail below.

Also, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail below.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2021, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2021 proposed rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we are preparing the data by first

applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 38 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2021 ratesetting, no CMHCs had geometric mean costs per day below the trim's lower limit of $18.89 or had geometric mean costs per day above the trim's upper limit of $572.65. Therefore, we do not exclude any CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2021 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR greater than one to the statewide hospital CCR (80 FR 70457). For this CY 2021 OPPS/ASC proposed rule ratesetting, there are no CMHCs that showed CCRs greater than one. Therefore, it is not necessary to default any CMHC to its statewide hospital CCR for ratesetting.

In summary, these data preparation steps did not adjust the CCR for any CMHCs with a CCR greater than one during our ratesetting process. We also do not exclude any CMHCs for other missing data or for failing the ±2 standard deviation trim, resulting in the inclusion of 38 CMHCs. There are 212 CMHC claims removed during data preparation steps because they either had no PHP-allowable codes or had zero payment days, leaving 9,369 CMHC claims in our CY 2021 proposed rule ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691) to calculate a CMHC APC geometric mean per diem cost.[83] The calculated CY 2021 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $104.00, a decrease from $121.62 calculated last year for CY 2020 ratesetting (84 FR 61347).

We investigated why the CY 2021 calculated CMHC APC geometric mean per diem cost had fallen below the cost floor established in the prior year (84 FR 61339 through 61344). We found that six providers, collectively representing 39.7 percent of all CMHC days, reported lower costs per day than those reported for the CY 2020 final rule ratesetting. These six providers heavily influenced the calculated geometric mean per diem cost for CY 2021. Because these providers had a high number of paid PHP days, and because the CMHC data set is so small (n=38), these providers had a significant influence on the calculated CY 2021 CMHC APC geometric mean per diem cost. In the case of PHPs provided by CMHCs, we have a low number of PHP providers in our ratesetting dataset (38 CMHCs compared to 363 hospital-based PHPs) that provide a small volume of services and, therefore, account for a limited amount of payments, relative to the rest of OPPS payments (total CY 2019 CMHC payments are estimated to be approximately 0.01 percent of all OPPS payments).

We are concerned that a CMHC APC geometric mean per diem cost of $104.00 would not support ongoing access to PHPs in CMHCs. This cost is roughly a 14.5 percent decrease from the final CY 2020 CMHC geometric mean per diem cost floor of $121.62. We believe access to partial hospitalization services and PHPs is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the CMHC APC 5853 is described as providing three or more partial hospitalization services per day (81 FR 79680), 85 percent of CMHC paid days in CY 2020 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP provider paid days are for providing four or more services per day (we refer readers to Table 30—Percentage of PHP Days by Service Unit Frequency of the proposed rule). Therefore, the CMHC APC 5853 is actually heavily weighted to the cost of providing four or more services. The per diem costs for CMHC APC 5853 have been calculated as $124.92, $143.22, and $121.62 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively. We do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from several high-utilization providers with low costs.

Therefore, rather than simply proposing the calculated CY 2021 CMHC APC geometric mean per diem cost of $104.00 for CY 2021 ratesetting, we are instead proposing to extend to CY 2021 and subsequent years the policy initially finalized only for CY 2020 (84 FR 61340 through 61341), to use the current year's CMHC APC geometric mean per diem cost (in this case, the CY 2021 CMHC APC geometric mean per diem cost), calculated in accordance with our existing methodology, but with a cost floor equal to $121.62 as established in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61345), as the basis for developing the proposed CY 2021 CMHC APC per diem rate. We believe using the CY 2020 CMHC geometric mean per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent CMHC PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for CMHC APC 5853. In this proposed rule, we used the most recent updated claims and cost data to calculate CY 2021 CMHC geometric mean per diem cost, which was $104.00. Because the CY 2021 CMHC calculated geometric mean per diem cost of $104.00 is less than the proposed cost floor (which equals the final CY 2020 CMHC APC geometric

[83] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR from the OPSF (or statewide CCR, where the overall CCR was greater than 1 to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

mean per diem cost of $121.62), the proposed CY 2021 CMHC geometric mean per diem cost is $121.62. Implementing the cost floor for CY 2021 would protect CMHCs since the CY 2021 calculated per diem cost of $104.00 results in an amount that is less than $121.62. We further propose that the established CMHC geometric mean per diem cost floor of $121.62 be extended to subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $121.62. We believe proposing the CMHC cost floor amount of $121.62 as the proposed CMHC APC geometric mean per diem cost for CY 2021 and subsequent years allows us to use the most recent or very recent CMHC claims and cost reporting data while still protecting provider access.

We estimate the aggregate difference in the (prescaled) CMHC geometric mean per diem costs for CY 2021 from proposing the CMHC cost floor amount of $121.62 rather than the calculated CMHC geometric mean per diem cost of $104.00 to be $1.3 million. We refer readers to section XX of this proposed rule for payment impacts, which are budget neutral.

Because the proposed CY 2021 calculated CMHC geometric mean per diem cost of $104.00 is less than the cost floor amount of $121.62, the proposed CY 2021 CMHC geometric mean per diem cost is $121.62.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2021 proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. The CY 2019 PHP claims included data for 436 hospital-based PHP providers for our calculations in this CY 2021 OPPS/ASC proposed rule.

Consistent with our policies as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying this CCR greater than 5 trim removed affected service days from two hospital-based PHP providers from our proposed ratesetting. However, 100 percent of the service days for these two hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed these providers entirely from our proposed ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Claims-Accounting.pdf.*

Overall, we removed 73 hospital-based PHP providers [(2 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ±3 SD limits)], resulting in 363 (436 total − 73 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the proposed CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based partial hospitalization services by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[84] The calculated CY 2021 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $243.94, which is an increase of 4.5 percent from $233.52 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61348). We believe that a hospital-based PHP APC geometric mean per diem cost of $243.94 best supports ongoing access to hospital-based PHPs. This cost is nearly a 5 percent increase from the final CY 2020 hospital-based PHP geometric mean per diem cost.

We stated that we believe access is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the hospital-based PHP APC 5863 is described as providing payment for the cost of three or more services per day (81 FR 79680), 89.3 percent of hospital-based PHP paid service days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP paid service days provide four or more services (we refer readers to Table 30.—Percentage of PHP Days by Service Unit Frequency in the proposed rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing four or more services. The per diem costs for hospital-based PHP APC 5863 have been calculated as $213.14, $208.09, and $222.76 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

As we noted for CMHCs above, we likewise do not believe that it is likely that the cost of providing hospital-based PHP services would suddenly decline when costs generally increase over time. In order to address concerns about potential fluctuations, which we believe could be influenced by data from a small number of providers with low service costs per day, we propose to use the CY 2021 hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the floor for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345), as the basis for developing the CY 2021 hospital-based PHP APC per diem rate. As part of this proposal, we propose that we would use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we did for CMHCs. We further propose that the established hospital-based geometric

[84] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

mean per diem cost floor of $222.76 be extended to CY 2021 and subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $222.76. We believe using the CY 2020 hospital-based PHP per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent hospital-based PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for hospital-based APC 5863.

While the cost floor would protect hospital-based PHPs if the CY 2021 calculated hospital-based PHP APC geometric mean per diem cost were less than $222.76, the calculated hospital-based PHP geometric mean per diem cost of $243.94 is greater than the floor, and therefore, we propose this calculated CY 2021 cost for hospital-based PHPs. As stated above, we believe this proposal allows us to use the most recent or very recent hospital-based PHP claims and cost reporting data while still protecting provider access.

Because the CY 2021 calculated hospital-based PHP geometric mean per diem cost of $243.94 is greater than the cost floor amount of $222.76, the proposed CY 2021 hospital-based PHP geometric mean per diem cost is $243.94. We refer readers to section XX. of this proposed rule for a discussion of payment impacts and the budget neutrality adjustment for OPPS rates.

c. Alternative Methodologies Considered

For this CY 2021 discussion of the proposed cost, we also considered proposing a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. The resulting 3-year collective PHP geometric mean per diem cost for CMHCs was $110.73, and the value was $243.31 for hospital-based PHP providers. While we believe that this option would support access to CMHCs better than the calculated geometric mean per diem cost of $104.00, it is significantly lower than the final CY 2020 CMHC geometric mean per diem cost of $121.62. As we discussed previously, we do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from several high-utilization providers with aberrantly low costs. We are further concerned that such an impact, though not observed for the CY 2021 proposed ratesetting, could affect hospital-based providers in the same way. Because each year's geometric mean per diem cost would be calculated from the prior 3 years, any similar fluctuations would therefore be reflected in the average for at least 3 years.

We also considered proposing a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. The resulting 4-year collective PHP geometric mean per diem cost for CMHCs was $119.68, and the value was $232.15 for hospital-based PHP providers. For CMHCs as well as hospital-based providers, these calculated 4-year geometric mean per diem cost values are slightly lower than the previous year's final geometric mean per diem costs ($121.62 and $233.52 respectively (84 FR 61347)). However, the value for hospital-based providers would be substantially lower than the calculated CY 2021 geometric mean per diem cost of $243.94. Fundamentally, our concern with the 3-year collective geometric mean is applicable to the 4-year collective as well, as any fluctuations observed would be reflected in the average for at least 4 years.

We believe that it is important to support access to partial hospitalization services in both CMHCs and in hospital-based PHPs, and note that hospital-based PHPs provide 82 percent of all paid PHP service days. Therefore, we believe that it is most appropriate to propose to use the calculated CY 2021 CMHC geometric mean per diem cost and the calculated CY 2021 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor for each provider type equal to the cost floor established in the CY 2020 final rule (84 FR 61339 through 61347). Because the floors established for CY 2020 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in final geometric mean per diem costs which would help to protect provider access by preventing wide fluctuation in the per diem costs for both CMHCs and hospital-based PHPs, we propose to extend these two floors to CY 2021 and subsequent years.

In summary, for CY 2021, we propose to use the calculated CY 2021 CMHC geometric mean per diem cost and the calculated CY 2021 hospital-based PHP geometric mean per diem cost, each calculated in accordance with our existing methodology, but with a cost floor for each provider type equal to the cost floor established in the CY 2020 final rule (84 FR 61339 through 61347), that is $121.62 for CMHCs and $222.76 for hospital-based providers, as the basis for developing the CY 2021 PHP APC per diem rates. Because the CY 2021 calculated geometric mean per diem cost for CMHCs is less than the cost floor amount of $121.62, we propose a CY 2021 geometric mean per diem cost for CMHCs of $121.62. In addition, because the CY 2021 calculated hospital-based PHP geometric mean per diem cost is greater than the hospital-based PHP cost floor amount of $222.76, we propose a CY 2021 hospital-based PHP geometric mean per diem cost of $243.94. In this proposed rule, we used the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs. The inclusion of a cost floor, which is based on very recent data, would protect CMHCs as their calculated per diem cost is less than the cost floor amount, but would not be relied upon for hospital-based PHPs for CY 2021.

These proposed CY 2021 PHP geometric mean per diem costs are shown in Table 28 and are used to derive the proposed CY 2021 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2021 PHP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[85]

[85] As discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more

TABLE 28: CY 2020 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2020 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$243.94

3. PHP Service Utilization Updates

a. Provision of Individual Therapy

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2019 claims data used for this CY 2021 proposed rule revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, CY 2017, and CY 2018 claims data as shown in the Table 29.

TABLE 29: PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of Individual Therapy on Days with 3 Services Only	Percent of Individual Therapy on Days with Four or More Services
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
CY 2018 Claims	2.3%	4.5%
CY 2019 Claims	1.0%	4.6%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%
CY 2018 Claims	3.8%	5.7%
CY 2019 Claims	3.6%	5.6%

As shown in Table 29, the CY 2019 claims show that CMHCs have slightly increased the provision of individual therapy on days with four or more services, compared to CY 2018 claims. However, on CMHC days with three services, the provision of individual therapy decreased sharply from the prior year CY 2018. This appears to follow a downward trend which started in CY 2016 and has continued through CY 2019. In comparing CY 2018 to CY 2019, we see that for CMHCs the provision of 3-service days also sharply increased (this increase is shown in Table 30 in subsection b below). The net effect of these two changes is that for all CMHC days with three or more services, the provision of individual therapy decreased from 4.4 percent in CY 2018 to 4.0 percent in CY 2019. We are concerned by this decrease in the provision of individual therapy among CMHCs from CY 2018, and will continue to monitor this trend. As we stated in the CY 2017 final rule with comment period (81 FR 79684 through 79685), the PHP is intensive in nature, and we believe that appropriate treatment for PHP patients includes individual therapy. We continue to encourage providers to examine their provision of individual therapy to PHP patients to ensure that patients are receiving all of the services that they may need.

For Hospital-based providers, the CY 2019 claims show that the provision of individual therapy has slightly decreased on days with only 3 services as well as days with four or more services. These very small decreases correspond with an overall decrease of less than one tenth of one percent in the provision of individual therapy on all days with three or more services, comparable with fluctuations in prior years.

information on scaling the weights, and for details on the final steps of the process that leads to final PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospital OutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing four or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of CMHC APC 5853 and hospital-based PHP APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2021 OPPS/ASC proposed rule, we used the CY 2019 claims data. Table 30 shows the utilization findings based on the 2019 claims data.

TABLE 30: PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2016	CY 2017*	CY 2018*	CY 2019*
CMHCs:				
Percent of Days with three services	4.8%	5.6%	6.9%	15.2%
Percent of Days with four services	70.3%	74.0%	71.2%	61.1%
Percent of Days with five or more services	24.9%	20.5%	21.9%	23.6%
Hospital-based PHPs:				
Percent of Days with three services	10.9%	9.8%	12.0%	10.6%
Percent of Days with four services	64.9%	56.4%	64.0%	66.6%
Percent of Days with five or more services	24.1%	33.9%	24.0%	22.7%

*May not sum to 100 percent by provider type due to rounding.

As shown in Table 30, the CY 2019 claims data used for proposed rule show that for CMHCs, utilization of 3 service days is increasing compared to the 3 prior claim years, whereas it is decreasing for hospital-based providers. Compared to CY 2018, in CY 2019 hospital-based PHPs provided fewer days with three services only, more days with four services only, and fewer days with five or more services. Compared to CY 2018, in CY 2019 CMHCs provided substantially more days with three services, fewer days with four services, and more days with five or more services.

The CY 2017 data were the first year of claims data to reflect the change to the single-tier PHP APCs. Since that time, we have observed a steady increase in the percentage of CMHC days with three services only. We are concerned by this increase, because as noted below, the intent of the PHP is for three-service days to be the exception, rather than the norm. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only three services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing three or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only three services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable minimum units of PHP services required in a PHP day to be 3 and explained that it was never our intention that three units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only three units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with three services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1) that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

C. Proposed Outlier Policy for CMHCs

For CY 2021, we propose to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G. of this CY 2021 OPPS/ASC proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996). We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. We propose to continue to calculate the CMHC outlier percentage according to previously established policies, and we do not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2021. To calculate the CMHC outlier percentage, we followed three steps:

- *Step 1:* We multiplied the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

(0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.

- *Step 2:* We estimated CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of this proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceeded the threshold, we multiplied that excess by 50 percent, as described in section VIII.C.3. of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of this proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we summed all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs − Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- *Step 3:* We determined the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1:

(Estimated CMHC Outlier Payments/ Total OPPS Outlier Payments).

In CY 2019, we designated approximately 0.01 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (83 FR 58996), based on this methodology. For CY 2021, we propose to continue to use the same methodology as CY 2020. Therefore, based on our CY 2021 payment estimates, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2021, excluding outlier payments. We propose to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). For CY 2021, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2021, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2021. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years.

For CY 2021, we propose to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). We propose to continue this policy for CY 2021.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our longstanding policies for identifying services that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we use to review the IPO list each year to determine whether or not any services should be removed from the list. The complete list of codes that describe services that will be paid by Medicare in CY 2021 as inpatient only services is included as Addendum E to this CY 2021 OPPS/ASC proposed rule, which is available via the internet on the CMS website.[86]

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

Currently, there are approximately 1,740 services on the IPO list. Under our current policy, we annually review the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available. We have established five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing services to determine whether or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

2. CY 2021 Proposal To Eliminate the IPO List

The IPO List was established with the implementation of the OPPS in the CY 2000 OPPS/ASC final rule with comment period (65 FR 18455). Using the authority under section 1833(t)(1)(B)(i) of the Act, the IPO List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the

[86] Note, the IPO list is proposed to be eliminated beginning in CY 2021, with all services being removed from the list over the course of a three-year transition period. The CY 2020 IPO List can be found here: Hospital Outpatient PPS, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.*

underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. For example, the list includes certain surgically invasive services on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies.

Since the IPO list was established in 2000, we have stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). We have reiterated this sentiment in rulemaking several times over the years, including in our discussion of the removal of total knee arthroplasty (TKA) from the IPO list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383) and most recently when we discussed removing total hip arthroplasty (THA) from the IPO List in the CY 2020 OPPS/ASC final rule with comment period, where we stated that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354).

In previous years, we received several comments from stakeholders who believe that we should eliminate the IPO list entirely and instead defer to the clinical judgment of physicians for decisions regarding site of service. For example, in the CY 2000 final rule with comment period, in response to the establishment of the IPO list, commenters stated that they believed CMS was making decisions, such as the appropriate site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18455, 18442). In the CY 2012 OPPS/ASC final rule with comment period, a number of commenters suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting (76 FR 74354). In the CY 2014 rulemaking, we again noted that some commenters requested that the IPO list be eliminated in its entirety (78 FR 75055). Stakeholders have also commented that the exclusion of services from payment under the OPPS is unnecessary and could have an adverse effect on advances in surgical care (65 FR 18442). Furthermore, some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. They have agreed that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting (65 FR 18442). Commenters have expressed concerns that without the IPO list, patient safety and care quality could decline, and have noted the potential for surgical complications in response to allowing specific procedures to be paid under the OPPS when performed in the outpatient setting for the Medicare population, such as TKA and THA.

Stakeholders have also supported the use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and as such are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay and therefore are not subject to medical review by Beneficiary and Family-Centered Care -Quality Improvement Organizations (BFCC–QIOs) for ''patient status'' (that is, site-of-service). We note that in the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. For CY 2021 and subsequent years, we propose to continue this 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We are also seeking comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted. For more information on these policies please refer to section X.B of this proposed rule.

While we agreed with commenters in previous rulemakings that the IPO list was necessary, we stated there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and that it would be inappropriate for us to establish payment rates for those services under the OPPS (78 FR 75055), recently we have reconsidered the various stakeholder comments requesting that we eliminate the IPO list and reevaluated the need for CMS to restrict payment for certain procedures in the hospital outpatient setting. We have concluded that we no longer believe there is a need for the IPO list in order to identify services that require inpatient care. Instead, we agree with past commenters that the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We believe that this change will ensure maximum availability of services to beneficiaries in the outpatient setting.

We also believe that since the IPO list was established, there have been significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting. We acknowledged in the CY 2000 OPPS/ASC final rule with comment period that we believed that emerging new technologies and innovative medical practice were blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many services (65 FR 18456). We also stated in the CY 2001 OPPS/ASC interim final rule with comment period that, over time, given advances in technology and surgical technique, many of the procedures that were on the IPO list at the time may eventually be performed safely in a hospital outpatient setting and that we would continue to evaluate services to determine whether they should be removed from the IPO list (65 FR 67826). Specifically, we stated that insofar as advances in medical practice mitigate concerns about these services being furnished on an outpatient basis, we would be prepared to remove them from the IPO list and provide for payment under the OPPS (65 FR 67826). Since that time, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures

such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes, such as improvements in pain management, that have reduced the inpatient length of stay and as well as the need for postoperative care following a surgical service. In consideration of these advancements, we have removed services from the IPO list that were previously considered to require inpatient care, including TKA in CY 2018 (82 FR 59385) and THA in CY 2020 (84 FR 61355). As medical practice continues to develop, we believe that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. Therefore, we believe that the IPO list is no longer necessary to identify services that require inpatient care.

We acknowledge the seriousness of the concerns regarding patient safety and quality of care that various stakeholders have expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. However, we believe that the evolving nature in of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. In the past, we stated that although hospitals must meet minimum safety standards through accreditation or state survey and certification of compliance with the CoPs that ensure a hospital is generally safe and an appropriate environment for providing care, we were concerned that those measures did not determine whether a particular service could be safely provided in the outpatient setting to beneficiaries (76 FR 74355). However, the CoPs are regulations that are focused on protecting the health and safety of all patients receiving services from Medicare enrolled providers. The CoPs are the baseline health and safety requirements for Medicare certification. Accrediting organizations and states and localities, through their licensure authorities, may have more specific and stringent requirements. Often professional organizations or other nonprofit organizations give additional guidance to health care providers to improve patient safety and quality of care. We note that the CoPs already require hospitals to be in compliance with applicable Federal laws related to the health and safety of patients (42 CFR 482.11) Additionally, there are numerous provisions in the hospital CoPs at 42 CFR part 482 that provide extensive patient safeguards and that provide enough room and flexibility to ensure that hospitals can follow nationally recognized standards of practice and of care where they are applicable and can adapt if those standards change over time through innovative new practices. For example, the hospital CoPs require that hospitals must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs (42 CFR 482.30). More specifically, the utilization review includes a review of the length of stay, medical necessity of admission and services rendered, and also looks to promote the most efficient use of available health facilities and services.

Additionally, as indicated in the 2020 Quality Strategy,[87] CMS has also continued to develop safety measures and tools, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey and the CMS' case management system, to help determine the safety and quality of the performance of procedures in the outpatient setting, to address concerns about the safety and quality of more varied, complex procedures performed in the outpatient setting. We believe that the aforementioned federally established CoPs, the CMS Quality Strategy and state and local safety requirements help ensure important patient safeguards for all patients, including Medicare beneficiaries. Further, although we believe it is important to pause certain medical contractor reviews for patient status to allow providers time to adjust to the proposed changes to the IPO, we note that the BFCC–QIO program's beneficiary case review contractors routinely address, and will continue to address any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. CMS' case management system currently allows QIOs and CMS to monitor the frequency and status of beneficiary quality of care complaints and other beneficiary appeals by topic, provider type, and geographic area. These numbers are compiled by the BFCC–QIO national coordinating and oversight review contractor and reported to the QIOs and CMS leadership on a weekly basis for monitoring purposes. As previously noted, although we propose to continue a 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, BFCC–QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, the medical necessity of the site of service, and will also continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary as noted in the CY 2020 OPPS/ASC final rule (84 FR 61365). Therefore, given CMS' increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we now believe that quality of care is unlikely to be negatively affected by the elimination of the IPO list. However, we are also requesting that commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on the quality of care.

Furthermore, some stakeholders have shared concerns with us that removing procedures from the IPO list and allowing them to be paid under the OPPS when performed in the outpatient setting may result in an increased financial burden for beneficiaries for certain complex services. Under current law, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. However, this cap applies to individual services, so if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary may be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. We emphasize that services included on the IPO list tend to be surgical procedures that would typically be the focus of the hospital outpatient stay and would likely be assigned to a

[87] Speech: Remarks by CMS Administrator Seema Verma at the 2020 CMS Quality Conference, *https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-2020-cms-quality-conference.*

comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered to be a single episode of care with one payment rate and one copayment amount instead of multiple copayments for each individual service. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, since because of their assignment to C–APCs, the inpatient deductible cap will apply to the entire hospital claim which is paid as a comprehensive service or procedure. In the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, our previously mentioned policy remains applicable, that is the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of this proposed rule.

After careful consideration of the need for the IPO list and taking into account the feedback that we have received since the OPPS was implemented, we believe that instead of maintaining a list of services that typically require inpatient care and are not paid under the OPPS, physicians should continue to use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We also believe that developments in surgical technique and technological advances in the delivery of services may obviate the need for the IPO list. Finally, we believe physician judgment, state and local regulations, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and other CMS quality and monitoring initiatives will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings in the absence of the IPO list. Therefore, we propose to eliminate the IPO list over a transitional period beginning in CY 2021. While we believe that the list could be eliminated in its entirety at this point, as explained in further detail below, we propose a transitional period.

Given the significant number of services on the list and that they will be newly priced under the OPPS, we recognize that stakeholders may need time to adjust to the removal of procedures from the list. Providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the inpatient prospective payment system or outpatient prospective payment system. Therefore, we propose to transition services off of the IPO list over a 3-year period, with the list completely eliminated by 2024. In accordance with this proposal, we propose to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

For CY 2021, we propose that musculoskeletal services would be the first group of services that would be removed from the IPO list. We believe it is appropriate to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements to postoperative processes we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we note that, more often than not, stakeholders' historical requests for removals were for musculoskeletal services. We also recognize that there is already a set of comprehensive APCs for musculoskeletal services for payment in the outpatient setting, which facilitates the removal of these types of services for CY 2021. Specifically, because we have previously removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, these APCs generally describe appropriate ranges and placements for these musculoskeletal codes being proposed for removal in CY 2021, which will allow for appropriate payment. We have identified 266 musculoskeletal services that we propose to remove from the IPO list for CY 2021.

3. Comment Solicitation on Order of Removal of Additional Clinical Families From the IPO List During the Transition To Complete Elimination of the IPO List

As stated above, we propose to eliminate the current IPO list of 1,740 services, starting with the 266 musculoskeletal-related services as provided in Table 31. We are requesting comments from the public on whether 3 years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemakings, until the IPO list is completely eliminated. Additionally, we seek comment on whether we should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list. We are also soliciting public comments on whether any of the musculoskeletal codes proposed for removal from the IPO list for CY 2021 may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XIII.C.1.c. of this proposed rule for a complete discussion of the ASC Covered Procedures List.

The 266 services that we propose to remove from the IPO list for CY 2021 and subsequent years, including the CPT/HCPCS code, long descriptor, and the proposed CY 2021 payment indicators, are included in Table 31 of this proposed rule.

In summary, given the developments in surgical technique and technological advances in the practice of medicine as well as the various safeguards discussed above, we propose to eliminate the IPO list over the course of the next 3 years, starting with the removal of 266 musculoskeletal-related services as provided in Table 31 in CY 2021. We propose to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that several safety mechanisms that will remain in place will ensure the safety of our beneficiaries and the quality of care, including, but not limited to, physician judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives.

Table 31 lists the procedures we propose to remove from the IPO list for CY 2021. These services and their proposed status indicators and APC assignments (if applicable) are included in Addendum B to this proposed rule as well.

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TABLE 31: PROPOSED MUSCULOSKELETAL-RELATED SERVICE REMOVALS FROM THE INPATIENT ONLY (IPO) LIST FOR CY 2021 (N=266)

CY 2020 CPT Code		CY 2020 Long Descriptor	Related Services	Proposed CY 2021 OPPS Status Indicator	Proposed CY 2021 OPPS APC Assignment
0095T		Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	22856	N/A	
0098T		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	22858	N/A	
0163T		Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	22858	N/A	
0164T		Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	22856	N/A	
0165T		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	22858	N/A	
0202T		Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral	63030	J1	5115

		column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine			
0219T		Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	63040	J1	5115
0220T		Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	63046	J1	5115
20661		Application of halo, including removal; cranial	20660	Q1	5113
20664		Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (for example, pediatric patients, hydrocephalus, osteogenesis imperfecta)	20660	Q1	5113
20802		Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	24545	J1	5116
20805		Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	24545	J1	5116
20808		Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	24545	J1	5116
20816		Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	24371	J1	5114
20824		Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	24371	J1	5114
20827		Replantation, thumb (includes distal tip to mp joint), complete amputation	24371	J1	5114

20838		Replantation, foot, complete amputation	24371	J1	5116
20955		Bone graft with microvascular anastomosis; fibula	27634	J1	5114
20956		Bone graft with microvascular anastomosis; iliac crest	27634	J1	5114
20957		Bone graft with microvascular anastomosis; metatarsal	27634	J1	5114
20962		Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	27634	J1	5114
20969		Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	27634	J1	5114
20970		Free osteocutaneous flap with microvascular anastomosis; iliac crest	27634	J1	5114
21045		Excision of malignant tumor of mandible; radical resection	21044	J1	5165
21141		Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	21150	J1	5165
21142		Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	21150	J1	5165
21143		Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	21150	J1	5165
21145		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21146		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21147		Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone	21150	J1	5165

		grafts (includes obtaining autografts)			
21151		Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	21150	J1	5165
21154		Reconstruction of midface bones with bone graft Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	21150	J1	5165
21155		Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	21150	J1	5165
21159		Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	21150	J1	5165
21160		Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	21150	J1	5165
21179		Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	21175	J1	5165
21180		Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	21175	J1	5165
21182		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes	21175	J1	5165

		obtaining grafts); total area of bone grafting less than 40 sq cm			
21183		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	21175	J1	5165
21184		Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	21175	J1	5165
21188		Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	21175	J1	5165
21194		Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	21175	J1	5165
21196		Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	21175	J1	5165
21247		Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	21175	J1	5165
21255		Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	21175	J1	5165
21268		Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	21172	J1	5165

21343		Open treatment of depressed frontal sinus fracture	21346	J1	5165
21344		Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	21346	J1	5165
21347		Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	21346	J1	5165
21348		Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	21346	J1	5165
21366		Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	21365	J1	5165
21422		Open treatment of palatal or maxillary fracture (lefort i type);	21445	J1	5165
21423		Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	21445	J1	5165
21431		Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	21445	J1	5165
21432		Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	21445	J1	5165
21433		Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	21445	J1	5165
21435		Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation	21445	J1	5165

		techniques (for example, head cap, halo device, and/or intermaxillary fixation)			
21436		Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	21445	J1	5165
21510		Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	21502	J1	5114
21602		Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	21601	J1	5114
21603		Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	21601	J1	5114
21615		Excision first and/or cervical rib;	21601	J1	5114
21616		Excision first and/or cervical rib; with sympathectomy	21601	J1	5114
21620		Ostectomy of sternum, partial	21601	J1	5114
21627		Sternal debridement	21601	J1	5114
21630		Radical resection of sternum;	21601	J1	5114
21632		Radical resection of sternum; with mediastinal lymphadenectomy	21601	J1	5114
21705		Division of scalenus anticus; with resection of cervical rib	21700	J1	5114
21740		Reconstructive repair of pectus excavatum or carinatum; open	21601	J1	5114
21750		Closure of median sternotomy separation with or without debridement (separate procedure)	21601	J1	5114
21825		Open treatment of sternum fracture with or without skeletal fixation	21813	J1	5114
22010		Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	22100	J1	5114
22015		Incision and drainage, open, of deep abscess (subfascial),	22102	J1	5114

		posterior spine; lumbar, sacral, or lumbosacral			
22110		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	22100	J1	5114
22112		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	22102	J1	5114
22114		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	22102	J1	5114
22116		Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	22100	N/A	N/A
22206		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	22102	J1	5114
22207		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	22102	J1	5114
22208		Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22210		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	22100	J1	5114

22212		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	22102	J1	5114
22214		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	22102	J1	5114
22216		Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	22103	N/A	
22220		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	22100	J1	5114
22222		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	22102	J1	5114
22224		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	22102	J1	5114
22226		Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22318		Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	22551	J1	5115
22319		Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	22551	J1	5115
22325		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	22554	J1	5115
22326		Open treatment and/or reduction of vertebral fracture(s) and/or	22554	J1	5115

		dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical			
22327		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	22102	J1	5115
22328		Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	22103	N/A	
22532		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	22554	J1	5116
22533		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	22554	J1	5116
22534		Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	22103	N/A	
22548		Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	22551	J1	5116
22556		Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	22554	J1	5116
22558		Arthrodesis, anterior interbody technique, including minimal	22554	J1	5116

		discectomy to prepare interspace (other than for decompression); lumbar			
22586		Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	22554	J1	5116
22590		Arthrodesis, posterior technique, craniocervical (occiput-c2)	22551	J1	5116
22595		Arthrodesis, posterior technique, atlas-axis (c1-c2)	22551	J1	5116
22600		Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	22551	J1	5116
22610		Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	22612	J1	5116
22630		Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	22612	J1	5116
22632		Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	22585	N/A	
22800		Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	22612	J1	5116
22802		Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	22612	J1	5116
22804		Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	22612	J1	5116

22808		Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	22612	J1	5116
22810		Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	22612	J1	5116
22812		Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	22612	J1	5116
22818		Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	22612	J1	5116
22819		Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	22612	J1	5116
22830		Exploration of spinal fusion	22612	J1	5115
22841		Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	22840	N/A	
22843		Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22844		Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22846		Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	22840	N/A	
22847		Anterior instrumentation; 8 or more vertebral segments (list	22840	N/A	

		separately in addition to code for primary procedure)			
22848		Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	22840	N/A	
22849		Reinsertion of spinal fixation device	22612	J1	5116
22850		Removal of posterior nonsegmental instrumentation (for example, harrington rod)	22612	J1	5115
22852		Removal of posterior segmental instrumentation	22612	J1	5115
22855		Removal of anterior instrumentation	22612	J1	5115
22857		Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	22856	J1	5116
22861		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5116
22862		Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	22856	J1	5116
22864		Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5115
22865		Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	22856	J1	5115
23200		Radical resection of tumor; clavicle	23155	J1	5114
23210		Radical resection of tumor; scapula	23155	J1	5114
23220		Radical resection of tumor, proximal humerus	23155	J1	5114

23335		Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	23334	J1	5073
23472		Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	23470	J1	5115
23474		Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	23473	J1	5115
23900		Interthoracoscapular amputation (forequarter)	23680	J1	5115
23920		Disarticulation of shoulder;	23680	J1	5115
24900		Amputation, arm through humerus; with primary closure	23680	J1	5115
24920		Amputation, arm through humerus; open, circular (guillotine)	23680	J1	5115
24930		Amputation, arm through humerus; re-amputation	24925	J1	5114
24931		Amputation, arm through humerus; with implant	23680	J1	5115
24940		Cineplasty, upper extremity, complete procedure	23680	J1	5115
25900		Amputation, forearm, through radius and ulna;	27709	J1	5115
25905		Amputation, forearm, through radius and ulna; open, circular (guillotine)	27709	J1	5115
25915		Krukenberg procedure	27709	J1	5114
25920		Disarticulation through wrist;	25922	J1	5114
25924		Disarticulation through wrist; re-amputation	25922	J1	5114
25927		Transmetacarpal amputation;	25922	J1	5113
26551		Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	20973	J1	5114
26553		Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	20973	J1	5114

26554		Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	20973	J1	5114
26556		Transfer, free toe joint, with microvascular anastomosis	20973	J1	5114
26992		Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	26990	J1	5114
27005		Tenotomy, hip flexor(s), open (separate procedure)	27006	J1	5114
27025		Fasciotomy, hip or thigh, any type	27027	J1	5114
27030		Arthrotomy, hip, with drainage (for example, infection)	27033	J1	5114
27036		Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	27033	J1	5114
27054		Arthrotomy with synovectomy, hip joint	27052	J1	5113
27070		Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	27065	J1	5114
27071		Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	27065	J1	5114
27075		Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	27067	J1	5114
27076		Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	27067	J1	5114
27077		Radical resection of tumor; innominate bone, total	27067	J1	5115

27078		Radical resection of tumor; ischial tuberosity and greater trochanter of femur	27067	J1	5115
27090		Removal of hip prosthesis; (separate procedure)	20680	J1	5073
27091		Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	20680	J1	5073
27120		Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	27067	J1	5115
27122		Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	27067	J1	5115
27125		Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	27130	J1	5115
27132		Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	27130	J1	5115
27134		Revision of total hip arthroplasty; both components, with or without autograft or allograft	27130	J1	5115
27137		Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	27130	J1	5115
27138		Revision of total hip arthroplasty; femoral component only, with or without allograft	27130	J1	5115
27140		Osteotomy and transfer of greater trochanter of femur (separate procedure)	27130	J1	5115
27146		Osteotomy, iliac, acetabular or innominate bone;	27179	J1	5114
27147		Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	27179	J1	5114
27151		Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	27179	J1	5114
27156		Osteotomy, iliac, acetabular or innominate bone; with femoral	27179	J1	5114

		osteotomy and with open reduction of hip			
27158		Osteotomy, pelvis, bilateral (for example, congenital malformation)	27179	J1	5114
27161		Osteotomy, femoral neck (separate procedure)	27179	J1	5114
27165		Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	27179	J1	5114
27170		Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	27179	J1	5114
27175		Treatment of slipped femoral epiphysis; by traction, without reduction	27179	J1	5114
27176		Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	27179	J1	5115
27177		Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	27179	J1	5114
27178		Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	27179	J1	5114
27181		Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	27179	J1	5114
27185		Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	27179	J1	5114
27187		Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	27235	J1	5114
27222		Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	27220	J1	5111
27226		Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	27235	J1	5114

27227		Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	27235	J1	5114
27228		Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	27235	J1	5114
27232		Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	27238	J1	5112
27236		Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	27235	J1	5114
27240		Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	27238	J1	5112
27244		Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	27235	J1	5114
27245		Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	27235	J1	5114
27248		Open treatment of greater trochanteric fracture, includes internal fixation, when performed	27235	J1	5114
27253		Open treatment of hip dislocation, traumatic, without internal fixation	27235	J1	5113

27254		Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	27235	J1	5113
27258		Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	27235	J1	5113
27259		Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	27235	J1	5113
27268		Closed treatment of femoral fracture, proximal end, head; with manipulation	27238	J1	5113
27269		Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	27238	J1	5112
27280		Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	27279	J1	5116
27282		Arthrodesis, symphysis pubis (including obtaining graft)	28730	J1	5115
27284		Arthrodesis, hip joint (including obtaining graft);	27279	J1	5116
27286		Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	27279	J1	5116
27290		Interpelviabdominal amputation (hindquarter amputation)	27279	J1	5116
27295		Detachment of hip joint	27279	J1	5116
27303		Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	27305	J1	5114
27365		Radical resection of tumor, femur or knee	27364	J1	5114

27445		Arthroplasty, knee, hinge prosthesis (for example, walldius type)	27447	J1	5115
27448		Osteotomy, femur, shaft or supracondylar; without fixation	27485	J1	5114
27450		Osteotomy, femur, shaft or supracondylar; with fixation	27485	J1	5114
27454		Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	27485	J1	5114
27455		Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	27485	J1	5114
27457		Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	27485	J1	5114
27465		Osteoplasty, femur; shortening (excluding 64876)	27485	J1	5114
27466		Osteoplasty, femur; lengthening	27485	J1	5114
27468		Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	27485	J1	5114
27470		Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	27485	J1	5114
27472		Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	27485	J1	5114
27486		Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	27477	J1	5115
27487		Revision of total knee arthroplasty, with or without	27477	J1	5115

		allograft; femoral and entire tibial component			
27488		Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	27485	J1	5114
27495		Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	27475	J1	5114
27506		Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	27509	J1	5114
27507		Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	27509	J1	5114
27511		Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	27509	J1	5114
27513		Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	27509	J1	5114
27514		Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	27509	J1	5114
27519		Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	27509	J1	5114
27535		Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	27532	J1	5114
27536		Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	27532	J1	5114
27540		Open treatment of intercondylar spine(s) and/or tuberosity	27532	J1	5114

		fracture(s) of the knee, includes internal fixation, when performed			
27556		Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	27532	J1	5114
27557		Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	27532	J1	5114
27558		Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	27335	J1	5114
27580		Arthrodesis, knee, any technique	27594	J1	5115
27590		Amputation, thigh, through femur, any level;	27594	J1	5116
27591		Amputation, thigh, through femur, any level; immediate fitting technique including first cast	27594	J1	5116
27592		Amputation, thigh, through femur, any level; open, circular (guillotine)	27594	J1	5116
27596		Amputation, thigh, through femur, any level; re-amputation	27499	J1	5114
27598		Disarticulation at knee	27428	J1	5115
27645		Radical resection of tumor; tibia	27637	J1	5114
27646		Radical resection of tumor; fibula	27637	J1	5114
27702		Arthroplasty, ankle; with implant (total ankle)	27447	J1	5115
27703		Arthroplasty, ankle; revision, total ankle	27447	J1	5115
27712		Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	27709	J1	5115
27715		Osteoplasty, tibia and fibula, lengthening or shortening	27709	J1	5115
27724		Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	27722	J1	5114

27725		Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	27722	J1	5114
27727		Repair of congenital pseudarthrosis, tibia	27722	J1	5114
27880		Amputation, leg, through tibia and fibula;	27884	J1	5116
27881		Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	27884	J1	5114
27882		Amputation, leg, through tibia and fibula; open, circular (guillotine)	27884	J1	5114
27886		Amputation, leg, through tibia and fibula; re-amputation	27884	J1	5114
27888		Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	27884	J1	5115
28800		Amputation, foot; midtarsal (for example, chopart type procedure)	28805	J1	5113
G0412		Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	27179	J1	5114
G0414		Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	27202	J1	5115
G0415		Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	27202	J1	5115

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X. Proposed Nonrecurring Policy Changes

A. Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we implemented a policy for CY 2020 and subsequent years to change the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. However, some groups of services were not subject to the change in the required supervision level and those services continue to have a minimum default level of supervision that is higher than general supervision.

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a PHE exists retroactive to January 27, 2020 [88] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19), and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists.[89] On March 13, 2020, the President of the United States declared the COVID–19 outbreak in the United States constitutes a national emergency,[90] beginning March 1, 2020. On March 31, 2020, we issued an interim final rule with comment period (IFC) to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the COVID–19. The goal of the IFC issued on March 31, 2020, was to provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health (85 FR 19232).

In the IFC issued March 31, 2020, we adopted a policy to reduce, on an interim basis for the duration of the PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. We also specified in the IFC issued March 31, 2020, that, for the duration of the PHE for the COVID–19 pandemic, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

These policies were adopted on an interim final basis for the duration of the PHE. However, we believe that these policies are appropriate outside of the PHE and should apply permanently. Therefore, we propose to adopt these policies for CY 2021 and beyond as described in more detail below.

1. Proposal To Allow General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

NSEDTS describe services that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS was established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72003 through 72013) as being direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner (§ 410.27(a)(1)(iv)(E)). In this case, initiation means the beginning portion of the NSEDTS which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. We originally established general supervision as the appropriate level of supervision after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component, particularly for CAHs and small rural hospitals.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. We made this change because we believe it is critical that hospitals have the most flexibility possible to provide the services Medicare beneficiaries need while minimizing provider burden. In the IFC issued March 31, 2020 (85 FR 19266), we assigned, on an interim basis, a minimum required supervision level of general supervision for NSEDTS services, including during the initiation portion of the service, during the PHE. Changing the minimum level of supervision to general supervision during the PHE gives providers additional flexibility to handle the burdens created by the PHE for the COVID–19 pandemic.

We believe changing the level of supervision for NSEDTS permanently for the duration of the service would be beneficial to patients and outpatient hospital providers as it would allow greater flexibility in providing these services and reduce provider burden, and thus, improve access to these services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner. In addition, as we explained in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61360), our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, including NSEDTS, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. It is important to remember that the requirement for general supervision for an entire NSEDTS does not preclude these hospitals from providing direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services including NSEDTS may involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.

In addition, CAHs and hospitals in general continue to be subject to conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services, including NSEDTS, to ensure that the medical services Medicare patients receive are properly supervised. CoPs for hospitals require Medicare patients to be under the care of a physician (42 CFR

[88] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[89] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[90] *https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.*

482.12(c)(4)), and for the hospital to ''have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital'' (42 CFR 482.22). The CoPs for CAHs (42 CFR 485.631(b)(1)(i)) require physicians to provide medical direction for the CAHs' health care activities, consultation for, and medical supervision of the health care staff. The physicians' responsibilities in hospitals and CAHs include supervision of all services performed at those facilities. In addition, physicians must also follow state laws regarding scope of practice.

Therefore, we propose to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. General supervision, as defined in our regulation at § 410.32(b)(3)(i), means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure; and as provided under § 410.27(a)(1)(iv)(C), certain non-physician practitioners can provide the required supervision of services that they can personally furnish in accordance with state law and all other applicable requirements. Because we propose a minimum required level of general supervision for NSEDTS, including during the initiation of the service, we propose to delete subparagraph (E) from the regulations at § 410.27(a)(1)(iv). We are seeking public comments on this proposal.

2. Proposal To Allow Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services Using Interactive Telecommunications Technology

Direct physician supervision was the standard set forth in the April 7, 2000 OPPS final rule with comment period (68 FR 18524 through 18526) for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals, including for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided to hospital outpatients. As we explained in the CY 2011 OPPS/ASC final rule with comment period, the statutory language of sections 1861(eee)(2)(B) and (eee)(4)(A) and section 1861(fff)(1) of the Act (as added by section 144(a)(1) of Pub. L. 110–275) defines cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs as ''physician supervised.'' More specifically, section 1861(eee)(2)(B) of the Act establishes that, for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs, ''a physician is immediately available and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed.'' As we explained in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, referencing the April 7, 2000 OPPS final rule (65 FR 18525)), the ''presumption'' or ''assumption'' of direct supervision means that direct physician supervision is the standard for all hospital outpatient therapeutic services. We have assumed this requirement is met on hospital premises because staff physicians would always be nearby in the hospital. In other words, the requirement is not negated by a presumption that the requirement is being met. Recently, some stakeholders suggested to us that we have the authority to change the default minimum level of supervision for pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services to general supervision because of the policy we adopted in CY 2020 to change the generally applicable minimum required level of supervision for most other hospital outpatient therapeutic services from direct supervision to general supervision (84 FR 61359 through 61363). For the reasons explained above, we disagree that we can change the default level of supervision for these services to general supervision under current law.

In the IFC issued March 31, 2020 (85 FR 19246), we implemented a policy for the duration of the PHE that allows the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to be met by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID–19 for the beneficiary or health care provider. While we adopted this policy to help improve the availability of rehabilitation services during the PHE and reduce the burden for providers, we also believe the policy to allow direct supervision provided by the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the end of the PHE. In some cases, depending upon the circumstances of individual patients and supervising physicians, we believe that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. For example, use of real-time audio and video telecommunications technology could allow a supervising physician to observe the patient during treatment as they interact with or respond to the in-person clinical staff. Thus, the supervising physician's immediate availability to furnish assistance and direction during the service could be met virtually without requiring the physician's physical presence in that location.

Therefore for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, we propose to change our regulation at § 410.27(a)(1)(iv)(D) to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We clarify that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. We are seeking public comments on this proposal.

B. Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the

patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-midnight presumption, which is related to the 2-midnight benchmark but is a separate medical review policy. The 2-midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. Thus, for purposes of the 2-midnight *presumption,* the ''clock'' starts at the point of admission as an inpatient.

With respect to the 2-midnight *benchmark,* however, the starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of determining whether the 2-midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving medically responsive services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment.

We continue to believe that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-midnight benchmark restricts the physician to a specific pattern of care, because the 2-midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient.

We also acknowledge that certain procedures may have intrinsic risks, recovery impacts, or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A regardless of the length of hospital time the admitting physician expects a particular patient to require.

2. Current Policy for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As mentioned previously, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, ''physician'') orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient-only under § 419.22 of the regulations. We finalized at § 412.3(d)(1) of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under

Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

We note that, in the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified previously that the patient nonetheless requires care on an inpatient basis. The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there was not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from eligibility for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for ''patient status.'' We explained that during this 2-year period, BFCC–QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

3. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-midnight rule is applicable once services have been removed from the IPO list. Services that are removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs.

BFCC–QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from eligibility for referral to RACs for noncompliance with the 2-midnight rule within the 2-calendar years following their removal from the IPO list.

As stated in section IX., we propose to eliminate the IPO list in CY 2021 with a transitional period of 3 years. For CY 2021, we propose to remove all musculoskeletal procedures from the IPO list. The elimination of the IPO list would mean that procedures currently on the IPO list would be subject to the 2-midnight rule (both the 2-midnight benchmark and 2-midnight presumption).

We believe that with the proposed elimination of the IPO list, the 2-midnight benchmark would remain an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. With more services available to be paid in the hospital outpatient setting, it would be increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the generally appropriate setting.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. With the proposed elimination of the IPO list, this policy would no longer be applicable. Instead, just as for services removed from the IPO list, the elimination of the IPO list would mean that any service that was once on the IPO list would be subject to the 2-midnight benchmark and 2-midnight presumption. This means that for services removed from the IPO list, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission would be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. Additionally, under the 2-midnight benchmark, services formerly on the IPO list would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

As finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are not eligible for referral to RACs for noncompliance with the 2-midnight rule within the first 2 calendar years of their removal from the IPO list. These procedures are not considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor are these procedures be reviewed by RACs for ''patient status.'' During the 2-year period, BFCC–QIOs have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes and does not result in a claim denial during the 2-year exemption period.

We continue to believe that in order to facilitate compliance with our payment policy for inpatient admissions, the 2-year exemption from certain medical review activities by the BFCC–QIOs for services removed from the IPO list under the OPPS in CY 2021 and subsequent years is appropriate. Accordingly, we propose to retain the existing 2-year exemption even in the event that we finalize the proposal to eliminate the IPO list. However, given that many more services would be removed from the IPO list during the proposed transition to elimination of the list, we seek comment on whether this 2-year period is appropriate or whether a longer or shorter period may be more appropriate in order for providers to gain experience with applying the 2-midnight rule to these services.

We also continue to believe that a 2-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, it is our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. Nonetheless, we solicit public comments regarding the appropriate period of time for this exemption. Commenters may indicate whether and why they believe the 2-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we propose to continue the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We encourage BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. Finally, while we propose to retain the current 2-year exemption period, given that many more services will be removed from the IPO as part of the transition towards the elimination of the list, we are seeking comment on whether that time period continues to be appropriate, or if a longer or shorter period may be more warranted.

C. Comment Solicitation on OPPS Payment for Specimen Collection for COVID–19 Tests

In the interim final with comment period (IFC) (85 FR 27604 through 27605) entitled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'', published on May 8, 2020, we created HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source).* This code was established in response to the significant increase in specimen collection and testing for COVID–19 in Hospital Outpatient Departments (HOPDs) during the COVID–19 Public Health Emergency (PHE). On January 31, 2020,[91] HHS Secretary Alex M. Azar II determined that a PHE exists for the United States retroactive to January 27, 2020. On April 21, 2020 Secretary Azar renewed, effective April 26, 2020, the determination that a COVID–19 PHE exists.[92] On July 23, 2020, Secretary Azar again renewed the determination that a COVID–19 PHE exists, effective July 25, 2020.[93]

In our prior review of HCPCS codes for the May 8, 2020 IFC, we did not identify a code that described the standalone services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. As stated in that IFC, we believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide extensive testing for the duration of the COVID–19 PHE. This code was created only to meet the need of the COVID–19 PHE and we stated that we expected to retire this code at

[91] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[92] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[93] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx.*

the conclusion of the COVID–19 PHE (85 FR 27605).

As stated in the aforementioned IFC (85 FR 27604 through 27605), we assigned HCPCS code C9803 to APC 5731—Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID–19 PHE. In accordance with Section 1833(t)(2)(B) of the Act, APC 5731—Level 1 Minor Procedures contains services similar to HCPCS code C9803. APC 5731—Level 1 Minor Procedures has a payment rate of $22.98 for CY 2020. HCPCS code C9803 was also assigned a status indicator of ''Q1.'' The Q1 status indicator indicates that the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we will make separate payment for the service under the OPPS. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of ''A'' on Addendum B of the OPPS.

As noted previously, the current determination of the existence of a COVID–19 PHE was recently renewed for another 90 day period, effective July 25, 2020. Given that the COVID–19 PHE is still active at this time and the possibility that it may need to be extended into 2021, for CY 2021 we propose to continue to assign HCPCS code C9803 to APC 5731 with a status indicator of ''Q1'', should the COVID–19 PHE continue to exist during CY 2021, with the presumption, as stated in the IFC that this code will be deleted when COVID–19 PHE ends. In this proposed rule, we are accepting public comments on the proposed APC and status indicator assignment for HCPCS code C9803 for CY 2021 (and remind commenters that the code is only active for the duration of the COVID–19 PHE under the IFC).

We are also soliciting public comments on whether we should keep HCPCS code C9803 active beyond the COVID–19 PHE and whether we should extend or make permanent the OPPS payment associated with specimen collection for COVID–19 tests after the COVID–19 PHE ends, including the reasoning for continuing to provide OPPS payment for this service as well as the timeframe for extending payment for this code. In the event we keep HCPCS code C9803 active after the COVID–19 PHE concludes, we are seeking public input on whether we should continue to assign HCPCS code C9803 to APC 5731—Level 1 Minor Procedures with a proposed status indicator of ''Q1''. In summary, we are requesting public comments on whether this code should continue to be payable under the OPPS to support COVID–19 testing beyond the conclusion of the COVID–19 PHE.

XI. Proposed CY 2021 OPPS Payment Status and Comment Indicators

A. Proposed CY 2021 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code.

For CY 2021, we are not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2020 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital--OutpatientRegulations-and-Notices-Items/CMS-1717-P.html?DLPage=1&DLEntries=10&10DLSort=2DLSortDir=descending*.

We are requesting public comments on the proposed definitions of the OPPS status indicators for CY 2021.

The complete list of the proposed payment status indicators and their definitions that would apply for CY 2021 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

The proposed CY 2021 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. Proposed CY 2021 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2021 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2020 and we propose to continue their use in CY 2021. The proposed CY 2021 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2021 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We believe that the existing CY 2020 definitions of the OPPS comment indicators continue to be appropriate for CY 2021. Therefore, we propose to use those definitions without modification for CY 2021.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2020 report.

A. Proposed OPPS Payment Rates Update

The March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress

update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2020 report for a complete discussion on these recommendations.[94] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2020 report, the Congress would need to change current law to enable us to implement its recommendations.

B. Proposed ASC Conversion Factor Update

In the March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[95] As a result, for CY 2021, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2021 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the MFP-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of this proposed rule, we propose to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts.

C. Proposed ASC Cost Data

In the March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program.[96]

We recognize that the submission of cost data could place additional administrative burden on most ASCs. We are interested in methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. We are not proposing any cost reporting requirements for ASCs in this CY 2021 OPPS/ASC proposed rule.

The full March 2020 MedPAC Report to Congress can be downloaded from MedPAC's website at: *http://www.medpac.gov*.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019 and 2020 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080, and 84 FR 61370 through 61410, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. Historically, we have defined surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of Current Procedural Terminology (CPT) codes for which separate payment is allowed under the OPPS when they are

[94] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, pp.94–95. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

[95] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

[96] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in 42 CFR 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (42 CFR 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and that are separately paid under the OPPS (72 FR 42478).

As we noted in the August 7, 2007 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. We now define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to

make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2021 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule (and respond to those comments in the CY 2021 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2021 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2022 OPPS/ASC final rule with comment period).

2. April 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2020 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2020 ASC quarterly update (Transmittal 10046, dated April 13, 2020, CR 11694), we added four new Level II HCPCS codes to the list of covered ancillary services. Table 32 lists the new Level II HCPCS codes that were implemented April 1, 2020, along with their proposed payment indicators for CY 2021. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2020 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 32: NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
C9053*	Injection, crizanlizumab-tmca, 1 mg	CH	K2
C9056**	Injection, givosiran, 0.5 mg	CH	K2
C9057#	Injection, cetirizine hydrochloride, 1 mg	CH	K2
C9058##	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	CH	K2

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2020 through the quarterly update CRs, as listed in Table 32. We propose to finalize their payment indicators in the CY 2021 OPPS/ASC final rule with comment period.

3. July 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2020 ASC quarterly update (Transmittal 10188, Change Request 11842, dated June 19, 2020), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 33 lists the new HCPCS codes that are effective July 1, 2020. The proposed comment indicators, payment indicators and payment rates for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2020 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC

assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

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TABLE 33: NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
C1748	Endoscope, single-use (that is, disposable), upper GI, imaging/illumination device (insertable)	NP	J7
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N1
C9059	Injection, meloxicam, 1 mg	NP	K2
C9061	Injection, teprotumumab-trbw, 10 mg	NP	K2
C9063	Injection, eptinezumab-jjmr, 1 mg	NP	K2
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	NP	K2
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	NP	N1
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	NP	Z2
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	NP	Z2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	NP	G2
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	NP	J8
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	G2
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	NP	J8
G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NP	J8

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NP	J8
J0223	Injection, givosiran, 0.5 mg	NP	K2
J0691	Injection, lefamulin, 1 mg	NP	K2
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	NP	K2
J0791	Injection, crizanlizumab-tmca, 5 mg	NP	K2
J0896	Injection, luspatercept-aamt, 0.25 mg	NP	K2
J1201	Injection, cetirizine hydrochloride, 0.5 mg	NP	K2
J1429	Injection, golodirsen, 10 mg	NP	K2
J1558	Injection, immune globulin (Xembify), 100 mg	NP	K2
J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	NP	K2
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	NP	K2
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	NP	N1
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	NP	K2
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	NP	K2
J9246	Injection, melphalan (evomela), 1 mg	NP	K2
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	NP	K2
Q4227#	Amniocore, per square centimeter	NP	N1
Q4228#	BioNextPATCH, per square centimeter	NP	N1
Q4229#	Cogenex amniotic membrane, per square centimeter	NP	N1
Q4230#	Cogenex flowable amnion, per 0.5 cc	NP	N1
Q4231#	Corplex P, per cc.	NP	N1
Q4232#	Corplex, per square centimeter	NP	N1
Q4233#	Surfactor or Nudyn, per 0.5 cc	NP	N1
Q4234#	Xcellerate, per square centimeter	NP	N1
Q4235#	Amniorepair or altiply, per square centimeter	NP	N1
Q4236#	CarePATCH, per square centimeter	NP	N1
Q4237#	Cryo-cord, per square centimeter	NP	N1

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
Q4238#	Derm-maxx, per square centimeter	NP	N1
Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	NP	N1
Q4240#	Corecyte, for topical use only, per 0.5 cc	NP	N1
Q4241#	Polycyte, for topical use only, per 0.5 cc	NP	N1
Q4242#	Amniocyte plus, per 0.5 cc	NP	N1
Q4244#	Procenta, per 200 mg	NP	N1
Q4245#	Amniotext, per cc	NP	N1
Q4246#	Coretext or Protext, per cc	NP	N1
Q4247#	Amniotext patch, per square centimeter	NP	N1
Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	NP	N1
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	K2
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	NP	K2
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	NP	J8
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	NP	R2
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	NP	R2
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	NP	J8
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	NP	J8
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	NP	J8
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	NP	J8
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	NP	J8
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	NP	J8

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	NP	J8

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR Part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR Part 1271.

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In addition, through the July 2020 quarterly update CR, we are establishing ASC payment for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2020. These codes are listed in Table 34, along with the proposed comment indicator and payment indicator. The CY 2021 proposed payment rate for these new Category III CPT codes can be found in Addendum BB. As noted above, the list of payment indicators and comment indicators used under the ASC can be found in Addendum DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 34: NEW CATEGORY III CPT CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 PI
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	NP	Z2
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	NP	N1

We are inviting public comments on the proposed payment indicators for the new CPT and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2020 through the quarterly update CRs, as listed in Tables 32, 33, and 34. We propose to finalize the payment indicators in the CY 2021 OPPS/ASC final rule with comment period.

4. October 2020 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

For CY 2021, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2020, would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We will invite public comments in the CY 2021 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

5. January 2021 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2021 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around

November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2021 OPPS/ASC final rule with comment period, January 2021 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2021, we will propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2021 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For new and revised CPT codes effective January 1, 2021 that were received in time to be included in this proposed rule, we propose the appropriate payment indicator assignments, and soliciting public comments on the ASC payment indicators. We will accept comments and finalize the payment indicators in the CY 2021 OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

For the CY 2021 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2021 can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). The CPT codes are assigned to comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new and revised CY 2021 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' We intend to include the final CPT code numbers the CY 2021 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2021 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2021. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed payment indicator and comment indicator for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new CPT codes that will be effective January 1, 2021 are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. The list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 35, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC.

TABLE 35: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2021 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d), including their potential designation as office-based. We reviewed the most recent claims volume and utilization data (CY 2019 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61376 through 61380).

Our review of the CY 2019 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.) resulted in our identification of seven covered

surgical procedures that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we propose to permanently designate as office-based for CY 2021 are listed as Table 36.

TABLE 36: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
11760	Repair of nail bed	G2	P3*
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3*
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2*
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	G2	P2*
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2*
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P3*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule.

We also reviewed CY 2019 volume and utilization data and other information for 18 procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,'' as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383). These procedures were surgical procedures that were designated as temporarily office-based in the CY 2019 OPPS/ASC final rule with comment period or were new CPT codes for CY 2020 that were designated as temporarily office-based. Of these 18 procedures, for each procedure, there were fewer than 50 claims in our data and no claims data for 11 of the 18 procedures described by CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985 and 93986. Therefore, we propose to continue to designate these procedures, shown in Table 37, as temporarily office-based for CY 2021. The procedures for which the proposed office-based designation for CY 2021 is temporary are indicated by an asterisk in Addendum AA to this proposed rule with comment period (which is available via the internet on the CMS website).

TABLE 37: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2020 OPPS/ASC PROPOSED RULE

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2	R2*
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

For the remaining seven procedures of the 18 procedures designated as temporarily office-based as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383), we propose to permanently assign an office-based designation for five of the procedures, represented by CPT codes

10007, 10011, 11102, 11104, and 11106. After reviewing CY 2019 volume and utilization data for these five procedures, the claims data are sufficient to indicate that these covered surgical procedures are performed predominantly in physicians' offices (greater than 50 percent of the time) and, therefore, we propose to permanently assign one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,''—to these codes for CY 2021 as shown in Table 38. For the two remaining procedures that had temporary office-based designations for CY 2020, described by CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion), utilization data are sufficient to indicate that these covered surgical procedures are not performed predominantly in physician's offices (performed in physician's offices less than 50 percent of the time) and, therefore, we propose to assign a non office-based payment indicator—''G2''—to these codes for CY 2021 as shown in Table 38.

TABLE 38: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	G2
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including ct guidance; first lesion	P2	G2
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P3*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

As discussed in the August 2, 2007 revised ASC payment system final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures temporarily as office-based until adequate claims data to assess their predominant sites of services, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

For CY 2021 we propose to designate 2 new CY 2021 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures in Table 39 would be predominantly performed in physicians' offices. We believe the procedures described by CPT codes 0596T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, including urethral measurement) and 0597T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); replacement) are similar to CPT code 55285 (Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: Urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone) which is currently on the list of covered surgical procedures and assigned a proposed payment indicator ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.—for CY 2021. While CPT code 52285 is not subject to office-based determinations as it is assigned an ''A2'' payment indicator, we note that this procedure is predominantly performed in a physician office setting (52 percent based on CY 2019 claims). As such, we propose to add CPT codes 0596T and 0597T in Table 39 to the list of temporarily office-based covered surgical procedures.

TABLE 39: PROPOSED CY 2021 PAYMENT INDICATORS FOR NEW CY 2021 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

(3) Comment Solicitation on Office-Based Exemption for Dialysis Vascular Access Procedures

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59036), the office-based utilization for CPT codes 36902 and 36905 (dialysis vascular access procedures) was greater than 50 percent. However, we did not designate CPT codes 36902 and 36905 as office-based procedures for CY 2019. These codes became effective January 1, 2017 and CY 2017 was the first year we had claims volume and utilization data for CPT codes 36902 and 36905. We shared commenters' concerns that the available data were not adequate to make a determination that these procedures should be office-based, and believed it was premature to assign office-based payment status to those procedures for CY 2019. For CY 2019, CPT codes 36902 and 36905 were assigned payment indicators of ''G2''—Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative weight.

As we stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61378), volume and utilization data for CPT code 36902 for CY 2018 showed the procedure was performed more than 50 percent of the time in physicians' offices. However, the office-based utilization for CPT code 36902 had fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs—from approximately 14,000 in 2017 to 38,000 in 2018. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believed it may have been premature to assign office-based payment status to CPT code 36902 for CY 2020. Therefore, for CY 2020, we finalized our proposal to not designate CPT code 36902 as an office-based procedure, but to continue to assign CPT code 36902 a payment indicator of ''G2''—non office-based surgical procedure paid based on OPPS relative weights. Additionally, CY 2018 volume and utilization data for CPT code 36905 showed the procedure was not performed more than 50 percent of the time in physicians' offices and we finalized our proposal to retain its payment indicator of ''G2''—non office-based surgical procedure based on OPPS relative weights for CY 2020.

For this CY 2021 OPPS/ASC proposed rule, we reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019. Similarly, CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices. Therefore, we are not proposing to designate CPT codes 36902 and 36905 as office-based procedures for CY 2021.

In past rulemaking, commenters have requested we permanently exempt dialysis vascular access procedures from office-based designations similar to our exemption for radiology services that involve certain nuclear medicine procedures and radiology services that involve contrast agents (42 CFR 416.171(d)(1) and (2)) (83 FR 59036). Commenters contended that an office-based designation for dialysis vascular access procedures (in particular CPT codes 36902 and 36905) would result in a lower ASC payment rate if frequently used additional services, which are often packaged under the ASC payment system but separately payable under the Physician Fee Schedule, are factored in to the analysis. Therefore, an office-based designation and payment at Physician Fee Schedule amounts under the ASC payment system may provide an inappropriate and lower global payment, after factoring in additional surgical procedures and/or ancillary items and services, when compared to the Physician Fee Schedule. Further, commenters have noted that ASCs are generally able to provide a wider array of dialysis vascular access procedures than a physician's office setting and at a lower Medicare payment rate than the hospital outpatient department setting. Providing an office-based ASC payment rate using PFS non facility PE RVUs for dialysis vascular access procedures may reduce the number of ASCs willing to perform such services and, subsequently, reduce beneficiary access for dialysis vascular access procedures in an ASC setting. Such an outcome may inadvertently encourage migration of dialysis vascular access procedures related services to the more expensive hospital outpatient department setting.

While current volume and utilization data shows that dialysis vascular access procedures are not predominantly performed in a physician's office setting, future data for office-based designations may illustrate a different result. ASC rates established at PFS non

facility PE RVU values may reduce the number of ASCs performing these procedures and inadvertently encourage greater utilization in the hospital outpatient department setting. While we are not currently proposing an exemption from payment at Physician Fee Schedule non facility PE RVU amounts, characterized by payment indicator ''P3'' for CY 2021, for dialysis vascular access procedures, we are contemplating implementing such an exemption in the future if necessary and are seeking comment on whether we might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking.

b. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2021

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received Food and Drug Administration (FDA) marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on our modified device-intensive criteria, for CY 2021, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2018 OPPS claims and cost report data available for the CY 2020 OPP/ASC proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2021, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2021 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment based on the standard ratesetting methodology to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system. 82 FR 59409.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit, is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.) Established ASC policy provides a reduction in ASC payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC covered device-intensive procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) Submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY2019 and subsequent calendar years. Therefore, we propose to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2021 and subsequent calendar years. Specifically, for CY 2021 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) Submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. We are not proposing any other changes to our policies related to no/cost full credit or partial credit devices.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC–CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders

Under our current regulations at 42 CFR 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 are surgical procedures that meet the general standards specified in 42 CFR 416.166(b) and are not excluded under the general exclusion criteria specified in 42 CFR 416.166(c). Specifically, under 42 CFR 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical

monitoring and care at midnight following the procedure. 42 CFR 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

For purposes of identifying procedures eligible to be added to the covered surgical procedure list, we define surgical procedures as those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category I and III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range (83 FR 59044–59045), that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We propose to continue to apply the revised definition of ''surgery'' we adopted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), which includes certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range, for CY 2021 and subsequent years.

As discussed above, section 1833(i)(1) of the Act requires the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed on an ambulatory basis in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. The report accompanying the legislation establishing section 1833(i)(1) of the Act explained that Congress intended procedures routinely performed on an ambulatory basis in a physician's office that do not generally require the more elaborate facilities of an ASC not to be included in the list of ASC covered procedures (H.R. Rep. No. 96–1167, at 390–91, reprinted in 1980 U.S.C.C.A.N. 5526, 5753–54).

In consideration of the statutory requirements and legislative history, in the implementing regulations of the current ASC system (effective in 2008), which we adopted in the August 2, 2007 final ASC rule (72 FR 42487), we excluded procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary if performed in the ASC setting. However, we agreed with stakeholders who have noted that ASCs are increasingly able to safely provide a greater range of services as medical practice continues to evolve and advance. We also believe that physicians play an important role and should be able to exercise their clinical judgment in making site-of-service determinations. Accordingly, CMS has continued to reexamine the process of how we determine which procedures are payable under Medicare when furnished in the ASC setting, keeping in mind the statutory requirement in section 1833(i)(1)(A) of the Act that the Secretary must specify those surgical procedures that are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, CAH or HOPD as part of reviewing and updating the list of procedures.

In the CY 2020 OPPS/ASC final rule with comment period, we added total knee arthroplasty and several coronary intervention procedures to the ASC–CPL (84 FR 61386 to 61397). Although the coronary intervention procedures involved blood vessels that could be considered major, based on our policy to consider the involvement of major blood vessels in the context of the clinical characteristics of the individual procedures and to maintain logical and clinical consistency in excluding procedures from the ASC–CPL (72 FR 42481), as well as our review of the clinical characteristics of the procedures and their similarity to other procedures that were included on the ASC–CPL, we believed these procedures could be safely performed in the ASC setting for appropriate beneficiaries. In the CY 2019 OPPS/ASC final rule with comment period, we also noted that in light of our conditions of coverage for ASCs, including 42 CFR 416.42, which require surgical procedures to be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC, we believe that the CfCs provide further assurance that services furnished in the ASC setting are held to a high standard of safety. While we acknowledged in the CY 2019 OPPS/ASC final rule with comment period that it could be more appropriate for certain beneficiaries to receive the coronary intervention procedures we were adding to the ASC CPL in a hospital-level setting, which typically has a higher level of emergency staff and equipment available, including onsite cardiac surgery backup, when compared to an ASC setting, we also noted that many beneficiaries could be ideal candidates to receive these services in an ASC setting and that beneficiaries and their physicians should be able to choose an appropriate site of service for surgeries based on the clinical characteristics of the patient and other factors (83 FR 59046). We continue to believe that relatively healthy and less complex patients would benefit from the shorter length of stay and reduced cost-sharing that would be expected in an ASC setting.

In the August 2, 2007 final rule with comment period establishing the revised ASC payment system, we discussed criteria for excluding procedures from the ASC–CPL (72 FR 42478 to 42484). In that same final rule, we adopted the current general standards and general exclusion criteria described above. One of the general exclusion criteria we established for the revised ASC payment system, at § 416.166(c)(6), excludes any procedure on the OPPS Inpatient Only (IPO) list, which is a list of procedures for which we do not make payment under the OPPS and that are typically performed in the hospital inpatient setting because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, and the underlying physical condition of the patient (65 FR 18456). We also stated that we believed that any procedures for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). We stated that we were committed to revising the ASC–CPL so that it excludes only those surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42479).

Also in the August 2, 2007 final rule with comment period, we discussed the exclusion of procedures involving major blood vessels, but we noted that it was important to maintain flexibility in our review of procedures for safe performance in the ASC setting, consistent with our past practice regarding this criterion (72 FR 42481). We discussed that there were some procedures already on the ASC list

being safely performed in ASCs that involve blood vessels that would generally be defined as major. We did not agree with commenters that it would be logical or clinically consistent for us to adopt a specific definition of major blood vessels to evaluate procedures for exclusion from ASC payment (72 FR 42481). We noted the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures.

We noted that we proposed to exclude surgical procedures that were expected to involve major blood vessels, major or prolonged invasion of body cavities, extensive blood loss, or that are emergent or life-threatening in nature from ASC payment, based on evaluation by our medical advisors (72 FR 42478–42479). We also noted that most of the procedures that our medical advisors identified as involving any of the characteristics listed in 42 CFR 416.65(b)(3) also require overnight or inpatient stays, reinforcing our belief that they should be excluded from ASC payment (72 FR 42478–42479). We also disagreed, at that time, that all procedures performed in HOPDs were appropriate for performance in ASCs. This was due in part to the fact that we believed that HOPDs were able to provide much higher acuity care, and because hospitals were subject to more stringent infection prevention, documentation, and patient assessment requirements than ASCs. As discussed in the August 2, 2007 final rule with comment period, ASCs were not required to meet patient safety standards consistent with those in place for hospitals (that is, hospital conditions of participation), and ASCs were not required, and are not currently required, to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain (72 FR 42479).

Many of these concerns have been addressed with the passage of time. We believe that our approach needs to evolve away from the criteria we established in 2008, in order to reflect the significant advances in medical practice and ASC capabilities over the last 12 years. In particular, we believe that significant advancements in medical practice, surgical techniques, medical technology, and other factors have allowed certain ASCs to safely perform procedures that were once too complex, including those involving major blood vessels and other general exclusion criteria. We acknowledge that ASCs and hospitals have different health and safety requirements. Despite this fact, ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals as well as meet Medicare conditions for coverage (see 42 CFR 416.40 through 416.54).

As mentioned above, in recent years, we have added procedures to the ASC–CPL that were largely considered hospital inpatient procedures in the past, such as TKA and certain coronary intervention procedures. As the practice of medicine has evolved, hospital lengths of stay have become shorter for many surgical procedures. Many services that used to be predominantly performed in the hospital inpatient setting are now routinely performed in the hospital outpatient setting on an ambulatory basis. Further, many procedures that are currently only payable as hospital outpatient services under Medicare fee-for-service are safely performed in the ASC setting for other payors. While we recognize that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, we note that careful patient selection can identify Medicare beneficiaries who are suitable candidates for these services in the ASC setting. Further, Medicare Advantage plans are not obligated to adopt the ASC–CPL as it exists in Medicare fee-for-service and, based on Medicare Advantage encounter data, many MA enrollees have had services performed in the ASC setting that are not currently payable under Medicare fee-for-service.

In addition, the COVID–19 pandemic has highlighted the need for more healthcare access points throughout the country. Many ASCs temporarily closed or significantly scaled back their operations based on state and federal recommendations to delay elective procedures during the public health emergency associated with COVID–19; while, some ASCs opted to temporarily enroll as hospitals. Looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible. Because the pandemic has forced many ASCs to close, thereby decreasing Medicare beneficiary access to care in that setting, we believe allowing greater flexibility for physicians and patients to choose ASCs as the site of care, particularly during the pandemic, would help to alleviate both access to care concerns for elective procedures as well as access to emergency care concerns for hospital outpatient departments.

(1) Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2021

Historically, we have reviewed the clinical characteristics of procedures and consulted with stakeholders and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166. Our regulation at 416.166(b) specifies the general standard criteria for covered surgical procedures, and requires that covered surgical procedures be surgical procedures: (1) That are separately paid under OPPS, (2) that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and (3) for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Additionally, 42 CFR 416.166(b) requires that a procedure not meet our exclusion criteria set forth in 42 CFR 416.166(c).

For CY 2021, we propose to continue to apply our current policies and criteria set forth in 42 CFR 416.2 and 42 CFR 416.166 for updating the ASC–CPL. In addition, we propose two alternative options for modifying our approach to adding surgical procedures to the ASC–CPL—(1) a nomination process for adding new procedures to the ASC–CPL, and (2) a broader approach under which we would revise our regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC–CPL. Under our first alternative proposal, a proposed nomination process along with modifications to certain regulatory criteria (as described later in this proposed rule), the effective date would be CY 2021 to accept and consider nominations and nominated procedures could be proposed to be added to the ASC–CPL beginning in the CY 2022 rulemaking. Under our second alternative proposal, we propose to revise our regulatory criteria by removing certain general exclusion criteria at 42 CFR 416.166(c) and under the revised criteria, we propose to add certain surgical procedures to the ASC–CPL beginning in CY 2021. We expect either of these options would have the effect of expanding the ASC–CPL, while maintaining the balance between safety and access for Medicare beneficiaries.

A. Standard ASC–CPL Review Process for CY 2021

For CY 2021, consistent with our current policy for reviewing the ASC–CPL, we conducted a review of HCPCS codes that currently are paid under the

OPPS, but not included on the ASC–CPL, and that meet the definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, and as explained in more detail below, we propose to update the list of ASC covered surgical procedures by adding eleven procedures to the list for CY 2021 as shown in Table 40 of this proposed rule. Procedures that we propose to add to the ASC–CPL for CY 2021 include total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others. After reviewing the clinical characteristics of these eleven procedures and consulting with our clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We have assessed each of the proposed procedures against the regulatory safety criteria in the regulation at 42 CFR 416.166(c) and believe that none of the procedures meet the general exclusion criteria.

Of the eleven procedures we propose to add, we believe that the THA procedure merits additional discussion in this proposed rule, given prior discussion of this procedure in past rulemaking, to explain our belief that the procedure meets existing safety criteria for purposes of adding this procedure to the ASC–CPL. In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the THA procedure, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), met the criteria to be added to the ASC–CPL. In the CY 2018 OPPS/ASC final rule with comment period, we noted that some commenters argued many ASCs are equipped to perform this procedure and orthopedic surgeons in ASCs are increasingly performing this procedure safely and effectively on non-Medicare patients and appropriate Medicare patients (82 FR 59412). Commenters also stated that adding THA to the ASC–CPLwould allow for greater choices in care settings for Medicare patients, would provide a more patient-centered approach to joint arthroplasty procedures, and that it may be safer in some cases to have joint arthroplasty procedures performed in an outpatient setting to prevent certain hospital-acquired infections (82 FR 59412).

However, other commenters recommended that ASCs obtain enhanced certification from a national accrediting organization that certifies an ASC meets higher quality standards and can safely perform joint arthroplasty procedures (82 FR 59412). Some commenters opposed adding THA to the ASC–CPL as they believed the vast majority of ASCs are not equipped to safely perform these procedures on patients and the vast majority of Medicare patients are not suitable candidates to receive ''overnight'' joint arthroplasty procedures in an ASC setting (82 FR 59412). For CY 2018, we did not finalize adding THA to the ASC–CPL, but noted that we would take commenters' suggestions and recommendations into consideration for future rulemaking.

In this CY 2021 OPPS/ASC proposed rule, we are seeking to continue to promote site neutrality, where possible, between the hospital outpatient department and ASC settings, and expanding the ASC–CPL to include as many procedures that can be performed in the HOPD as reasonably possible will advance that goal. Further, we believe that there are at least a subset of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics. We believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for THA. We believe THA would meet our existing regulatory requirements established under 42 CFR 416.2 and 416.166(b) and (c) for covered surgical procedures in the ASC setting. In light of this information and the public comments submitted in support of adding THA to the ASC–CPL in response to our CY 2018 public comment solicitation, we propose to add THA to the ASC–CPL in CY 2021, as shown in Table 40.

We propose to add a total of eleven procedures, displayed in Table 40 with their HCPCS code long descriptors, to the list of ASC covered surgical procedures for CY 2021. We seek public comment on our proposal, including any medical evidence or literature to support the commenters' views on whether or not we should add any of these procedures to the ASC–CPL for CY 2021. In addition, we also seek comment on the two alternative proposals described below. Note that under both alternative proposals, we still propose to add the eleven procedures proposed under this section for CY 2021.

(1) Proposed Changes to General Exclusion Criterion for Procedures Requiring Inpatient Care To Conform to Proposed Changes to the Underlying Requirements Under the OPPS

As described in section IX.B. of this proposed rule, CMS is proposing to eliminate the OPPS IPO list and amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that retaining § 416.166(c)(6) will ensure that procedures that are largely performed on an inpatient basis and cannot be safely performed on an ambulatory basis will not be added to the CPL prematurely. As a result, we propose to revise the regulatory language and modify this standard to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020.

(2) Alternative Proposals Under Consideration for CY 2021

For CY 2021, we are continuing to build on our efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC–CPL in order to further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, often at a lower cost than other options. In light of the current national Public Health Emergency related to COVID–19 and its anticipated lasting effects on the health care system, we also believe a broader approach for adding procedures to the ASC–CPL would allow for a more efficient use of healthcare resources and infrastructure. An expansion of the ASC–CPL would maximize the ability of ASCs to divert patients that can be safely treated in an ASC setting away from the hospital setting, which would preserve the capacity of hospitals to treat more acute patients. Expanding the procedures placed on the ASC–CPL would also build on the policy changes we have made in recent years to further site neutrality between the HOPD and ASC settings. In light of these objectives, we propose two alternatives to our existing policy of adding procedures to the ASC–CPL, each of which would further support these goals.

a. Alternative Proposal One

Under the first approach, we propose and may finalize in the final rule a policy to adopt a nomination process for

adding new procedures to the ASC–CPL. This process would involve soliciting recommendations from external stakeholders, like medical specialty societies and other members of the public, for procedures that may be suitable candidates to add to the ASC–CPL. As discussed in greater detail below, under this approach, we would provide parameters as guidelines that we would strongly encourage stakeholders to consider in nominating procedures for the ASC–CPL. CMS anticipates that stakeholders, such as specialty societies who specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions on which additional procedures may reasonably and safely be provided in an ASC context.

While members of the public may already suggest procedures to be added to the CPL through meetings with CMS or through public comments to the proposed rule, we believe it may be beneficial to adopt a streamlined process under which the public, particularly specialty societies who are very familiar with procedures in their specialty, can to nominate procedures based on the latest evidence available as well as input from their memberships. We believe that this revised process could increase transparency in how we are assessing procedures to add to the ASC list and also help ensure that we are assessing the list in a more streamlined fashion.

We propose that the nomination process would be conducted through annual notice and comment rulemaking and the final determinations regarding nominated procedures would be decided in the final rule. Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the previous calendar year, with all nominations received by that date considered in the next applicable rulemaking cycle, likely the rulemaking for the following calendar year. Any nominations received after that date, including those received through comments as part of the rulemaking cycle, would generally be addressed in rulemaking the following year. CMS would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures and the additional parameters specified in detail below. We propose to establish the nomination process in the CY 2021 final rule to begin in CY 2021, for surgical procedures that could be added to the ASC–CPL beginning in CY 2022. We propose a process under which nominated procedures would be included in the proposed rule for that calendar year, along with a summary of the policy and factual justification for adding or not adding each procedure, which would allow members of the public to assess and provide comment on nominated procedures during the public comment period. After reviewing comments provided during the public comment period, CMS would finalize adding the procedures that meet the requisite criteria to the ASC–CPL in the final rule. In the event that CMS disagrees with any procedures nominated, we would provide a specific rationale in the final rule. In certain cases, CMS may need to defer a final determination regarding a nominated procedure to future rulemaking, in order to provide sufficient time to evaluate and make the most appropriate decision about the nominated procedure.

Under this alternative proposal, we would update the ASC–CPL by considering whether nominated procedures meet the requirements for covered surgical procedures under 42 CFR 416.166, as we propose to amend them. This would include 42 CFR 416.166(b), which sets out the general standards for covered surgical procedures, requiring that surgical procedures be separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We also propose to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (c)(5) such that nominated procedures would not have to meet those criteria. Further, we propose to modify § 416.166(c)(6) to align the regulatory text with the proposed elimination of the IPO list. Finally, we propose that nominated procedures would need to meet the general exclusions at 42 CFR 416.166(c)(7) and (c)(8).

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, this alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. In other words, we would not accept any nominations for procedures to add to the ASC–CPL if the procedure is on the CY 2020 IPO list. We are retaining the criteria §§ 416.166(c)(6) through (8) and eliminating the five criteria currently at §§ 416.166(c)(1) through (5) because we believe that the general standards at 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five characteristics. We believe that this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

As noted above, under this alternative proposal, stakeholders would nominate procedures to be added to the ASC–CPL by March 1 of a year to be considered for addition to the ASC–CPL for the next calendar year. As stated above, and similar to the second alternative described in the next section, we propose that nominated procedures must meet the general standards for covered surgical procedures under 42 CFR 416.166(b) and the general exclusions under 42 CFR 416.166(c)(6) through (8), subject to the modifications we propose for 42 CFR 416.166(c)(6), to reflect the proposed phase out of the IPO list under the OPPS, as discussed in section IX.B of this proposed rule. Specifically with respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard because the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. Under this alternative proposal, a nomination process would be added at 42 CFR 416.166(d), explaining the process that would be used to review and update the list of ASC procedures each year. We propose to remove the general exclusions under 42 CFR 416.166(c)(1) through (c)(5), as discussed above.

Additionally, we are also proposing to adopt the following parameters for stakeholders to consider and specifically address in nominating procedures to add to the ASC–CPL.

These parameters are meant as general guidelines, not requirements, and we seek public comment on these suggested parameters including language changes, recommendations for additional parameters, potential unintended implications of the parameters we propose, and whether we should finalize these parameters if this alternative proposal is finalized in the CY 2021 final rule:

- Does the procedure involve a risk of life-threatening complications?

Example: Does the procedure involve high or low risk of life-threatening complications?

○ If the procedure involves lower risk for life-threatening complications, it may be a reasonable candidate for consideration.

○ If the procedure involves a higher risk, consider the next question.

- Is there a need for specialized resources, not generally available in an ASC, to mitigate the risk of one or more life-threatening complications?

Example: Are specialized resources, not generally available in an ASC, needed to mitigate the risk of one or more life-threatening complications from the procedure?

○ If specialized resources are not needed for this procedure, it may be a reasonable candidate for consideration.

○ If specialized resources are needed to reduce the patient's risk of life-threatening complications, consider the next question.

- What is the average length of time for patients to be stabilized for transport to another facility?

Example: If a complication occurs, can the patient generally be stabilized in transport for at least 90 minutes?

○ If a patient undergoing the procedure cannot be stabilized for 90 minutes, this would be a serious consideration regarding the appropriateness of performing the procedure for Medicare beneficiaries in the ASC setting.

○ If a patient undergoing this procedure can be stabilized for 90 minutes, please consider the next question.

- Are resources and providers required for intervention generally available at nearby facilities for intervention?

Example: If a patient is transferred to another institution, can a team be mobilized and prepared to intervene within a relatively short period from complication onset, inclusive of transport? Although the length of this time period may vary, it should be enough time to ensure the patient has a viable chance of rescue from the other facility.

○ If a team cannot be mobilized and prepared to intervene within this period, then this procedure should not be considered for the ASC–CPL.

○ If a team can be mobilized and prepared to intervene within this period, then this procedure could be a reasonable candidate for consideration.

We believe a nomination process will take time to develop and stakeholders will need time to consider and evaluate potential nominations. We propose to implement this process for CY 2021 in order to accept nominations for procedures to be added to the ASC CPL beginning in CY 2022.

b. Alternative Proposal Two

We also considered another alternative approach that would allow for more immediate changes to the ASC–CPL for CY 2021 and beyond. Specifically, under this alternative proposal, we propose, and may finalize in the CY 2021 final rule, to keep the existing general standards under 42 CFR 416.166(b) that currently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website, separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. However, under this alternative proposal, we would eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (c)(5). We considered whether these five exclusionary criteria may no longer be necessary to determine what procedures can be safely added to the ASC–CPL because many ASCs are currently able to safely provide services with these characteristics based on prior stakeholder feedback and public comments we have received.

We explored whether it is appropriate to remove the general exclusion criteria. This would allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgment to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications. Under this alternative proposal, we would keep the remaining three general exclusion criteria at 42 CFR 416.166(c)(6) through (c)(8), as the original reasons we adopted them in CY 2008 continue to exist, subject to the proposed modifications to 416.166(c)(6). These criteria would continue to prohibit the addition of certain procedures to the ASC CPL, namely those that are either designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020, which can only be reported using a CPT unlisted surgical procedure code, and any procedures that are otherwise excluded under 42 CFR 411.15. We propose to retain these criteria and eliminate the previous five criteria because we believe that the general standards alone are sufficient guardrails to ensure, along with appropriate patient selection and complex medical judgment of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve these five characteristics.

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of this proposed rule. Therefore, we would propose to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. In other words, not all procedures on the current (that is, CY 2020) IPO list would necessarily meet the remaining revised criteria to be added to the ASC–CPL. However, because any procedure not on the IPO can be performed safely on an ambulatory basis in the hospital outpatient setting, we believe that the remaining criteria in 42 CFR 416.166, most notably the exclusion of services that are on the current IPO list, could sufficiently limit the expansion of the ASC–CPL to those services that can be safely performed on an ambulatory basis. As previously mentioned, we are proposing to retain the criteria in §§ 416.166(c)(6) through (8) and eliminate the five criteria currently at §§ 416.166(c)(1) through (5) because we believe that the general standards at 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five

characteristics. We believe that this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

We identified approximately 270 potential surgery or surgery-like codes that we believe would meet the proposed revised criteria for being added to the ASC–CPL under 42 CFR 416.166. That is, we reviewed these procedures and found that they would meet the proposed revised regulatory requirements that would be in effect if we were to adopt this alternative proposal. Specifically, the identified procedures under this alternative proposal were surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, that have not been designated as requiring inpatient care under 419.22(n) as of December 31, 2020, that can be reported without using a CPT unlisted surgical procedure code, and are not otherwise excluded under 42 CFR 411.15.

Additionally, while several of the identified procedures may typically require hospital care that lasts beyond midnight, we expect that appropriately selected patient population in the ASC setting would be healthier and less complex and would likely not require active monitoring or medical care past midnight beyond the procedure. We believe that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act. We would retain the general standard criteria, as we believe these criteria are sufficient to ensure that procedures meet the statutory requirements and can be safely performed in ASCs. We seek public comment on whether any of these procedures would typically require care after midnight, and, therefore, should not be added to the ASC–CPL.

We believe that this alternative proposal could have beneficial effects for Medicare beneficiaries and healthcare professionals. For beneficiaries, expansion of the ASC–CPL would increase access to procedures in ambulatory surgery settings, often at a lower cost. ASCs and healthcare professionals would also benefit from this proposal as this expansion would better utilize the potential of existing healthcare resources and expand the capacity of the healthcare system. Further, under this alternative, physicians would have greater flexibility to divert patients who can be safely treated in the ASC setting away from hospitals and preserve hospital capacity for more acute patients.

We acknowledge that this approach is a departure from the existing criteria that we established effective beginning in 2008. However, we believe that this approach would expand and build upon our 2008 policy intent. In the August 2, 2007 final rule with comment period, we discussed criteria for procedures excluded from the ASC–CPL under the revised ASC payment system (72 FR 42478 to 42484). However, although there are differences, much of the underlying rationale we used to develop the August 2, 2007 final rule revised criteria remains true under the broader CY 2021 proposal. For example, in the August 2, 2007 final rule with comment period, we indicated that we believed that any procedure for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). Much like we are considering now, we excluded from the ASC list any procedure on the IPO list, and committed to excluding surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42478 to 42479). Although there are some differences when comparing our CY 2008 criteria and the proposed CY 2021 criteria, such as removing several of the original general exclusion criteria, permitting the addition of procedures to the ASC–CPL that would have been prohibited by those criteria, and the different accreditation requirements and conditions of participation requirements between HOPDS and ASCs, these concerns have largely been addressed by the progress in medical practice and ASC capabilities in the twelve years since the criteria were developed as previously noted. In particular, given advances in the practice of medicine and the evolving nature of ASCs, we believe ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. As previously mentioned, although ASCs and hospitals have different health and safety requirements, many ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals. Each of these requirements provides additional safeguards for the health and safety of Medicare beneficiaries receiving surgical procedures in an ASC.

(c) Comment Solicitation on Potential Revisions to the ASC Conditions of Coverage if Alternative 2 Is Adopted

Providers and suppliers participating in Medicare must comply with our regulations (variously called Conditions of Participation (CoPs), Conditions for Coverage (CfCs), Conditions of Certification, or Requirements) in order to begin and continue participating in the Medicare program. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. For ambulatory surgical centers (ASCs), the CfCs are located at 42 CFR part 416.

Section 416.2 of our regulations defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting.

The ASC CfCs were first published on August 5, 1982 (47 FR 34082), and have since been amended several times. The ASC CfCs currently contain 14 separate conditions that include requirements regarding compliance with State licensure law; governing body; surgical services; quality assessment and performance improvement; environment; medical staff; nursing services; medical records; pharmaceutical services; laboratory and radiologic services; patient rights; infection control; patient admission, assessment and discharge; and emergency preparedness.

As noted previously, CMS agrees with stakeholders that as medical practice continues to evolve and advance, ASCs are increasingly able to safely provide a greater range of services. The proposed expansion of the ASC–CPL would allow physicians to exercise their clinical judgment in making site-of-service determinations that are appropriate and also beneficial to the patient. In recent years, more complex surgical procedures that have been identified to be appropriate for certain Medicare patients have been added to the ASC–CPL. For example, effective CY 2020,

the total knee arthroplasty (TKA) procedure was added to the ASC–CPL as part of the rulemaking process (84 FR 61385). CMS agreed with public commenters that there is a small subset of Medicare beneficiaries who may be suitable candidates to receive TKA in an ASC setting based on their clinical characteristics. In addition, certain coronary intervention procedures were added even though these procedures involve blood vessels that could be considered major; it was appropriate to add these procedures in our view based upon our belief that the procedures should be considered in the context of proper patient selection and clinical characteristics.

The current ASC CfCs provide the baseline health and safety standards that accommodate the oversight of a broad spectrum of ASC facility types that include services such as orthopedics, ophthalmology, endoscopy, dental and other specialty practices. We believe the current ASC CfCs provide sufficient flexibility and protection to patients such that they would not need to be revised even if we were to adopt a significant expansion of the ASC–CPL as outlined under the second alternative proposal described in the above section. The current ASC CfCs require the ASC, governing body and the medical staff to be responsible for the policies and procedures that are reflective of the patients that are served in the ASC. The ASC is directly responsible for ensuring the ASC and medical staff evaluate their patient base and ensure appropriate precautions and services are in place for all surgical procedures performed in their facility.

The CfCs are one part of our coordinated requirements and expectations for ASCs, which also include reporting of quality measures under the ASCQR program. Both the CfCs and quality reporting program would remain in place to ensure patient safety during and after any changes to the ASC–CPL, but we request comments on whether the CfCs or quality metrics should also change in response to an expanded range of services that may be paid under Medicare in the ASC setting. We refer readers to section XV.B. of this proposed rule regarding ASCQR Program quality measures.

In the event that CMS were to finalize a proposal to allow more invasive and lengthy surgical procedures in ASCs, we are requesting comment on whether or not the ASC CfCs should be revised in the CY 2021 final rule to ensure that our health and safety standards are sufficiently updated to reflect the additional range of complex services that would be added to the ASC–CPL, and, if so, the recommended revisions. For example, the current surgical services CfC regulations under 42 CFR 416.42(a)(1)(I) require that a physician must examine the patient to evaluate the risk of the procedure to be performed while the regulations at 42 CFR 416.42(a)(1)(II) require a physician or anesthetist as defined at § 410.69(b) to examine the patient to evaluate the risk of anesthesia. We seek public comment on whether or not these risk evaluations should be expanded to be more prescriptive and require additional elements such as requiring the referring doctor to submit pertinent health information and attest that an individual patient can safely undergo the specified procedure(s) in an ASC and, if appropriate, may adopt such changes in the CY 2021 final rule.

In addition, current standards at 42 CFR 416.46(a) require a registered nurse be available for emergency treatment whenever there is a patient in the ASC. We are soliciting comment on whether we should add an additional CfC at § 416.46 to require that an adequate number of nurses be on duty in the ASC at all times that the ASC has patient(s), consistent with the standard required of hospitals under § 482.23(b) and the associated guidance in the Medicare State Operations Manual A–0392 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf*). Similar to the hospital requirements, we anticipate that ASCs must take into account the specific types of services being furnished and the acuity of the patients in ensuring that there is adequate nursing staff available.

Further, standards under 42 CFR 416.44(e) also currently require personnel trained in the use of emergency equipment and cardiopulmonary resuscitation be available whenever there is a patient in the ASC. Despite ASCs having access to local emergency services to transfer patients to the nearest appropriate hospital for continued care, we request comment on whether, in the final rule for CY 2021, we should change the requirements to increase the mandatory level of certification for personnel. For example, with respect to the current regulations at 42 CFR 416.44(e), we are interested in whether or not CMS should require the presence of staff certified to provide Advance Cardiac Life Support (ACLS) in the ASC to respond to any life threatening emergencies, and be capable of providing a full and complete medical resuscitation response in the ASC, to stabilize the patient before an emergency transfer to the closest hospital.

We also request comment on whether we should make specific requirements in the CfC regulations at 42 CFR 416.52(a) for particular patient conditions or more complex and invasive surgical procedures ASCs would need to meet and for any evidence that would support such recommendations. As mentioned previously, we also request comments on possible additions or revisions to the quality measures under ASCQR if additional procedures are added to the ASC–CPL.

We note the most useful comments are those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

In summary, in light of the possibility of significantly expanding the ASC–CPL for CY 2021, we are considering whether changes to the ASC CfCs may be appropriate. As noted above, the current ASC CfCs provide the baseline health and safety standards that accommodate the oversight of a broad spectrum of ASC facility types that include a variety of services. We believe the current ASC CfCs provide sufficient flexibility and protection to patients such that they would not need to be revised even if we were to adopt a significant expansion of the covered ASC–CPL, however, we seek comment on whether certain revisions may be necessary and may adopt such revisions as final in the CY 2021 final rule.

(4) Summary of Proposals

For CY 2021, we propose to add eleven procedures using the standard ASC–CPL review process under our current regulations. In addition, we include two alternative proposals that we may finalize for CY 2021. One alternative is to establish a nomination process for CY 2021, which would allow us to propose to add nominated procedures beginning in CY 2022. Under this proposal, external stakeholders, such as professional specialty societies, would nominate procedures that can be safely performed in the ASC setting based on the requirements in the ASC regulations, revised as described in this proposed rule (that is, retaining the general standard criteria and eliminating five of the general exclusion criteria), along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, we propose to revise the ASC–CPL criteria under 42 CFR

416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, we propose to add approximately 270 potential surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list. We propose to finalize only one of these alternative proposals, and we welcome public comment as to which policy should be adopted in the final rule.

After consideration of priorities discussed above, we believe that these proposed policies strike an appropriate balance of between flexibility for physicians to exercise their complex medical judgment in factoring in patient safety considerations and flexibility for patients to choose from more settings of care in which to receive surgical procedures.

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TABLE 40: PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2021 UNDER STANDARD REVIEW PROCESS

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
21365	Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27412	Autologous chondrocyte implantation, knee	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J8

TABLE 41: PROPOSED ADDITIONS TO THE ASC-CPL UNDER SECOND ALTERNATIVE PROPOSAL CONSIDERED FOR CY 2021

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
20100	Exploration of penetrating wound (separate procedure); neck	G2
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	G2
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21365	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	G2
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27412	Autologous chondrocyte implantation, knee	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	G2
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	G2
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	G2
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	G2
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, dacron, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	G2
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	G2
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	G2
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J8
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2
44950	Appendectomy;	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	G2
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2
55970	Intersex surgery; male to female	G2
55980	Intersex surgery; female to male	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	G2
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57335	Vaginoplasty for intersex state	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	J8
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	G2
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	N1
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	J8
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	G2
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	G2
C9758	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator
	esophagogastric junction (egj), with implantation of pulse generator, includes programming	
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	G2
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	G2
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	G2
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	G2
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	G2
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	J8
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	G2
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	J8
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	J8
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	J8
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	G2
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	J8

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D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59028 through 59080), we updated the CY 2018 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2017 data, consistent with the CY 2019 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2019 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2018 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2018 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2018 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2021

We propose to update ASC payment rates for CY 2021 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use the geometric mean to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We propose to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC proposed rule. Therefore, we propose to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2021 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2021 MPFS nonfacility PE RVU-based amount or the proposed CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2020, for CY 2021 we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with those procedures and would continue to be paid separately under the ASC payment system.

c. Proposed Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of this CY 2021 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this CY 2021 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that procedure. Under our new policy,

where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. For CY 2020, this policy only affected HCPCS code 0308T, which had very low claims volume (7 claims from CY 2018 used for CY 2020 ratesetting in the OPPS). Additionally, we amended § 416.171(b) of the regulations to reflect the new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at § 416.171(b)(2) requires the payment of the device portion of a device-intensive procedure at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We added paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the equivalent procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Based on our review of CY 2019 claims using our standard ratesetting methodology, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, there was a single claim containing CPT code 0308T that was unable to be used for the CY 2021 OPPS/ASC proposed rule ratesetting process as it was packaged into a comprehensive APC. Because our claims accounting logic does not assign the costs of individual procedures provided as part of a comprehensive APC to the APC that would otherwise apply the costs for CPT code 0308T were not assigned to the APC for that procedure, APC 5495 (Level 5 Intraocular Procedures). As a result, there was no available cost data from CY 2019 claims data to construct relative payment weights for CPT code 0308T. As discussed in section III.D.2., under the OPPS, we propose to establish the payment weight for the CY 2021 OPPS for CPT code 0308T using the CY 2020 OPPS final rule median cost of $20,229.78 and relative payment weight as reflecting the most recent claims and cost data. Similarly, as there are no usable claims with CPT code 0308T from CY 2019, which we would normally use for this CY 2021 proposed rule under our standard ratesetting methodology, to establish an appropriate payment rate in CY 2021 for CPT code 0308T using the most recent claims and cost data, we propose to establish the payment rate under the ASC payment system for CY 2021 using CY 2020 final rule OPPS median cost of $20,229.78 and relative payment weight as reflecting the most recent available claims and cost data.

However, CPT code 0308T was designated as a low volume device-intensive procedure in CY 2020. For CY 2020, under the low-volume procedure payment policies in effect through CY 2019, the available claims data would have resulted in a payment rate of approximately $111,019.30 for CPT code 0308T when performed in the ASC setting, which would have been several times greater than the OPPS payment rate. Therefore, for CY 2020 we finalized our policy to limit the ASC payment rate for low-volume device intensive procedures to a payment rate equal to the OPPS payment rate for the procedures. This policy had the effect of limiting the ASC payment rate for CPT code 0308T to the applicable payment rate under the OPPS (which was $20,675.62 in CY 2020). Therefore, for this CY 2021 proposed rule, we propose to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T, which is $20, 994.57 in this proposed rule. Further, in the absence of claims data for this proposed rule, we also propose in this CY 2021 OPPS/ASC proposed rule to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T. We will continue to monitor the claims available for ratesetting as they become available in preparation for the CY 2021 OPPS/ASC final rule.

The proposed payment rate for covered surgical procedures for CY 2021, including CPT code 0308T, are listed in Addendum AA of this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in section IV. of this CY 2021 OPPS/ASC proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of this CY 2021 OPPS/ASC proposed rule, for CY 2019, we finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, even though payment for these drugs continues to be packaged under the OPPS. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as

radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2021

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2021 OPPS and ASC payment rates and subsequent year payment rates. We also propose to continue to set the CY 2020 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2021 and subsequent year payment rates.

Based on our quarterly updates for April and July 2020, we propose to add CPT 0598T (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)), CPT 0599T (Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)), C9762 (Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging), and C7963 (Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging) as covered ancillary services.

Covered ancillary services and their proposed payment indicators for CY 2021 are listed in Addendum BB of this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the PFS final rates, the proposed payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments

Section 6082 of the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,'' also referred to as the ''SUPPORT for Patients and Communities Act'' (SUPPORT Act) (Pub. L. 115–271) was enacted on October 24, 2018. Section 6082(a) of the SUPPORT Act requires in part that the Secretary: ''(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives; (ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and (iii) shall consider the

extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.'' Section 6082(b) of the SUPPORT Act requires that the Secretary conduct a similar type of review in ambulatory surgical centers.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59066 through 59072), we finalized the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also finalized conforming changes to § 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We added a new § 416.164(b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, we finalized a change to § 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39424 through 39427), we reviewed payments under the ASC for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39426), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61177), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only FDA-approved drug that meets these criteria is Exparel.

We conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 to 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Our updated review of claims data for the CY 2020 proposed rule showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting.

(4) Evaluation and CY 2021 Proposal for Payment for Non-Opioid Alternatives

Over the last 2 years, we have conducted detailed evaluations of our payment policies regarding the use of opioids and non-opioid alternatives. We have reviewed multiple years of Medicare claims data, all public comments received on this topic, and studies and data from external stakeholders. Each of these reviews have led to the consistent conclusion that CMS's packaging policies are not discouraging the use of non-opioid alternatives or impeding access to these products, with the exception of Exparel, the only non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting.

Section 6082(a) of the SUPPORT Act also provides that after an initial review, the Secretary can conduct subsequent reviews of covered payments as the Secretary deems appropriate. In light of the fact that CMS has conducted a thorough review of payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, we do not believe that conducting a similar review for CY2021 would be a fruitful effort. After careful consideration, we believe we have fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, as described in the CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Current claims data suggest that CMS' current policies are having a positive impact on the utilization of non-opioid alternatives, including Exparel. A preliminary claims analysis showed that the total units of Exparel have increased over the last year. From CY 2015 to CY 2018, we saw an annual decline in the total units of Exparel furnished in the ASC setting, with 244,756 total units provided in CY 2015 dropping to 60,125 total units provided in CY 2018. In CY 2019, ASCs furnished a total of 1,379,286 units of Exparel. Due to this positive trend that reflects the increased use of non-opioid treatment for pain, we do not believe that further changes are necessary under the ASC payment system for non-opioid pain management drugs that function as a surgical supply in the ASC setting. Therefore, for CY 2021, we propose to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

E. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

• Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*

• We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

• In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2021

We did not receive any requests for review to establish a new NTIOL class for CY 2021.3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2021.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. ASC Payment and Comment Indicators for CY 2021

For CY 2021, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2021 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 202a compared to the CY 2020 descriptors are included in ASC Addenda AA and BB to this proposed rule were labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the proposed rule. Proposed comment indicator ''NP'' meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

For the CY 2021 update, we propose to add ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—) to ASC Addendum DD1 to this proposed rule (which is available via the internet on the CMS website). New drug HCPCS codes that do not have claims data or payment rate information are currently assigned to OPPS status indicator ''E2''—Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). These codes are

categorized and included in the ASC payment system as nonpayable codes and are currently assigned an ASC payment indicator ''Y5''—Non-surgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made—because that is the ASC payment indicator that currently best describes the status of these HCPCS codes. However, ''Y5'' assignments include both those drug codes that would not be integral to the performance of a surgical procedure and are therefore not payable in the ASC payment system and those codes that may become separately payable in the ASC payment system. Since there is not a separate payment indicator that describes the subset of drug codes that will become payable when claims data or payment information is available the existing ASC payment indicators cannot currently communicate the distinction between these two classes of drugs. Therefore, for CY2021 and subsequent calendar years, we propose to add ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 to this proposed rule (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2021 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2020 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2021.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this CY 2021 OPPS/ASC proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d) (10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical

Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

For CY 2021, the proposed CY 2021 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01 and 17–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the state (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2021 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system equal to what would be the current expenditures based on the scaled ASC payment weights. In this way we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

Consistent with our established policy, we propose to scale the CY 2021 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2019, we propose to compare the total payment using the CY 2020 ASC relative payment weights with the total payment using the CY 2021 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2020 and CY 2021. We propose to use the ratio of CY 2020 to CY 2021 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2021. The proposed CY 2021 ASC weight scalar is 0.8494. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, we have

available 90 percent of CY 2019 ASC claims data.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2019 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2019 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file is available to the public as a supporting data file for this proposed rule and is posted on the CMS website at: *http://http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPayment System.html.*

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor.

Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2021, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2021 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2021 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2020 ASC wage indexes and the total adjusted payment using the proposed CY 2021 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2020 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2021 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2021 ASC wage index budget neutrality adjustment) to the CY 2020 ASC conversion factor to calculate the proposed CY 2021 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a MFP-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2021 is projected to be 3.0 percent, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), based on IHS Global Inc.'s (IGI's) 2019 fourth quarter forecast with historical data through the third quarter of 2019.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed MFP adjustment for CY 2021 is projected to be 0.4 percentage point, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739) based on IGI's 2019 fourth quarter forecast.

For CY 2021, we propose to utilize the hospital market basket update of 3.0 percent minus the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this CY 2021 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the hospital market basket update of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.4 percentage point MFP adjustment. Therefore, we propose to apply a 0.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or MFP adjustment), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period.

For CY 2021, we propose to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the MFP-adjusted hospital market basket update of 2.6 percent discussed above, which results in a proposed CY 2021 ASC conversion factor of $48.984 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in

addition to the quality reporting/MFP-adjusted hospital market basket update of 0.6 percent discussed above, which results in a proposed CY 2021 ASC conversion factor of $48.029.

3. Display of Proposed CY 2021 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2021 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the PFS rates that would be effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

The proposed payment rates included in addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2021 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2021. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

For CY 2021, we propose to add a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Proposed CY 2021 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2021. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2021 payment rate displayed in the ''Proposed CY 2021 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2021 Payment Weight'' column was multiplied by the proposed CY 2021 conversion factor of $48.984. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The proposed CY 2021 ASC conversion factor uses the CY 2021 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus a projected MFP adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2021 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2021 Payment'' column displays the proposed CY 2021 national unadjusted ASC payment rates for all items and services. The proposed CY 2021 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2021.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2019 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; and 84 FR 61410 through 61420) for the regulatory history of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

4. Proposal To Codify Statutory Authority for Hospital OQR Program

The Hospital OQR Program regulations are codified at 42 CFR

419.46. We propose to update the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required to be submitted on measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual OPD fee schedule increase factor. We propose to redesignate the existing paragraphs (a) through (h) as paragraphs (b) through (i) and codify the Hospital OQR Program's statutory authority at new paragraph § 419.46(a). Because of the proposed redesignations, the cross-references throughout § 419.46 are also proposed to be updated.

Table 42 shows the correlation between the cross-references proposed to be removed and added if the proposed redesignations are finalized.

TABLE 42: CORRELATION BETWEEN THE CROSS-REFERENCES PROPOSED TO BE REMOVED AND ADDED IF THE PROPOSED REDESIGNATIONS ARE FINALIZED

Proposed Newly Redesignated Paragraphs	Proposed Cross-references to be Removed	Proposed Cross-references to be Added
(d)(3)(ii) and (iii)	(c)(2)	(d)(2)
(g)(2)(viii)	(e)(1)	(f)(1)
(i)(1)	(h)(2) and (3)	(i)(2) and (3)
(i)(3)	(h)(2)	(i)(2)
(i)(3)(ii)	(h)(3)(i)(A)	(i)(3)(i)(A)

We request public comment on this proposal.

We refer readers to section XIV.E. of the preamble of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2023 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at 42 CFR 419.46(h)(1) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for removal of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[97] We codified this policy at 42 CFR 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles (77 FR 68472). In this case, we would promptly remove the measure and notify hospitals of its removal, and confirm the removal of the measure in the next rulemaking cycle. We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized a process to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns.[98] We codified this policy at 42 CFR 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at 42 CFR 419.46(h)(3) an updated set of factors[99] and policies for determining whether to remove measures from the Hospital OQR Program. We refer readers to that final rule with comment period for a detailed discussion of our policies regarding measure removal factors. We are not proposing any changes to these policies in this proposed rule.

4. Summary of Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410 through 61420) for a summary of the previously finalized Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years.

We are not proposing any changes to the previously finalized measure set.

[97] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[98] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

[99] We note that we previously referred to these factors as ''criteria'' (for example, 77 FR 68472 through 68473); we now use the term ''factors'' in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

Table 43 summarizes the previously finalized Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years.

TABLE 43: HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2023 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**

† We note that NQF endorsement for this measure was removed.
* Measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

5. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.* We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We are not proposing any changes to these policies in this proposed rule.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

a. Codification

In the 2009 OPPS/ASC final rule with comment period (73 FR 68778), we finalized that hospitals sharing the same

CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. While we previously finalized this policy, it was not codified. In this proposed rule, we propose to codify this policy by adding language at the redesignated paragraph (d)(1). If finalized, the newly redesignated paragraph (d)(1) would specify that ''Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.'' We are soliciting public comment on our proposal.

b. Overall Hospital Quality Star Rating

In this proposed rule, we propose a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital OQR Program. We refer readers to section XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of this proposed rule for details.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at 42 CFR 419.46(a) in that final rule with comment period.

In this proposed rule, we propose to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We propose to revise existing § 419.46(a)(2), proposed redesignated § 419.46(b)(2), by replacing the term ''security administrator'' with the term ''security official.'' If finalized, the newly redesignated paragraph (b)(2) would read: ''Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section.'' We invite public comment on our proposal to replace the term ''security administrator'' with ''security official'' and codify this change.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these procedural requirements regarding participation status at 42 CFR 419.46(a) and (b).

In this proposed rule, we propose to revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy; submission of this form was removed as a program requirement in the CY 2019 OPPS/ASC final rule (83 FR 59103 to 59104). We also propose to update internal cross-references as a result of the redesignations discussed under section XIV.A.4. of this proposed rule. If finalized as proposed, the newly redesignated § 419.46(c) would specify that ''A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in § 419.46(b) in order to participate in any future year of the Hospital OQR Program.'' Our proposal also includes updated cross-referenced provisions in the newly redesignated § 419.46(c). We are soliciting public comment on our proposal.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439) where we finalized our policies for data submission deadlines. We codified these submission requirements at 42 CFR 419.46(c). The submission deadlines for the CY 2023 payment determination and subsequent years are illustrated in Table 44.

TABLE 44: CY 2023 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2021 (April 1 - June 30)	11/1/2021
Q3 2021(July 1 – September 30)	2/1/2022
Q4 2021 (October 1 - December 31)	5/1/2022
Q1 2022 (January 1 - March 31)	8/1/2022

To align with statute, in this proposed rule, we propose one change to our submission deadlines. We propose that all deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order would be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order.

We propose to revise our policy regarding submission deadlines at existing § 419.46(c)(2), proposed redesignated § 419.46(d)(2). If finalized, the newly redesignated paragraph (d)(2) would specify that ''All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.'' We invite public comment on our proposal.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2022 payment determination and subsequent years:

- *OP–2:* Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- *OP–3:* Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- *OP–18:* Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- *OP–23:* Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2023 Payment Determination and Subsequent Years

Currently, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2022 payment determination and subsequent years:

- *OP–8:* MRI Lumbar Spine for Low Back Pain (NQF #0514);
- *OP–10:* Abdomen CT—Use of Contrast Material;
- *OP–13:* Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- *OP–32:* Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- *OP–35:* Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- *OP–36:* Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. We are not proposing any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures in this proposed rule.

5. Data Submission Requirements for Measures for Data Submitted via a Web-Based Tool for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the CMS QualityNet website (*www.qualitynet.org* for a discussion of the requirements for measure data submitted via the CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) system secure portal) for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized quality measures will require data to be submitted via a CMS web-based tool for the CY 2023 payment determination and subsequent years with the exception of OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for which data submission remains voluntary:

- *OP–22:* Left Without Being Seen (NQF #0499);
- *OP–29:* Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- *OP–31:* Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

6. Population and Sampling Data Requirements for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We are not proposing any changes to these policies in this proposed rule.

7. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. Per the previously finalized policy, the Hospital OQR Program implemented a 4-month review and corrections period for chart-abstracted measure data, which runs concurrently with the data submission period. During the review and corrections period for chart-abstracted data, hospitals can enter, review, and correct data submitted directly to CMS for the chart-abstracted measures.

b. Web-Based Measures

In this proposed rule, we propose to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. Hospitals would have a review and corrections period for web-based measures, which would run concurrently with the data submission period. The review and corrections period for web-based measures is from the time the submission period opens to the submission deadline. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. The expansion of the existing policy for chart-abstracted measures to data submitted via the CMS web-based tool would accommodate a growing diversity of measure types in the Hospital OQR Program. We are soliciting public comment on our proposal.

c. Codification of the Review and Corrections Periods for Measure Data Submitted to the Hospital OQR Program

We note that the previously finalized policy relating to the review and corrections period for chart-abstracted measures has not yet been codified. Therefore, in this proposed rule, we propose to codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool. Specifically, we propose to add a new paragraph (4) at existing § 419.46(c), proposed redesignated § 419.46(d). If finalized, the new paragraph (d)(4) would read: ''*Review and Corrections Period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.'' We are soliciting public comment on our proposal.

8. Hospital OQR Program Validation Requirements

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(e) for our policies regarding validation. In this proposed rule, while we are not proposing changes to our validation policies, we propose to codify certain previously finalized policies; these are discussed in more detail in section XIV.D.8.b.

a. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

(1) Background

In the CY 2018 final rule (82 FR 59441 through 59443), we finalized a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. Under the informal process, hospitals that were selected and received a score for validation may request an educational review to better understand the results. A hospital has 30 calendar days from the date the validation results are made available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review (82 FR 59442). In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback (82 FR 59442). CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital (82 FR 59442). In the CY 2018 final rule (82 FR 59441 through 59443), we (1) formalized this process; and (2) specified that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. We are not proposing any changes to this finalized policy in this proposed rule.

(2) Proposed Codification of Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

The previously finalized policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59442), has not yet been codified at 42 CFR 419.46. In this proposed rule, we propose to codify those policies by adding a new paragraph (4) to existing § 419.46(e), proposed redesignated § 419.46(f). If finalized, the new paragraph (f)(4) would specify that ''Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.'' We invite public comment on this proposal.

9. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), and 42 CFR 419.46(f) for our reconsideration and appeals procedures.

In alignment with our proposal to change submission deadlines in section XIV.D.1. of this proposed rule, we propose one change to our reconsideration deadlines. We propose

that all deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order would be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order. Specifically, we propose to remove ''the first business day on or after'' from existing § 419.46(f)(1), proposed redesignated § 419.46(g)(1), to ensure the language of the regulatory text regarding deadlines for reconsideration requests is consistent with 42 U.S.C. 416(j). If finalized, the newly redesignated paragraph (g)(1) would read: ''A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS.'' We invite public comment on our proposal.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02) / (1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the

reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2021

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2021 annual payment update factor. For this CY 2021 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which when multiplied by the proposed full conversion factor of $83.697 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.016. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For this CY 2021 OPPS/ASC proposed rule, we propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2021, the proposed reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 83.697 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 82.065. We note that the proposed reporting ratio can be applied to the full national unadjusted payment rates to determine reduced national unadjusted payment rates.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of the CY 2020 final rule (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Initiative and our approach in evaluating quality program measures.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CYs 2014 through 2020 OPPS/ASC final rules with comment period (78 FR 75122; 79 FR 66966 through 66987; 80 FR 70526 through 70538; 81 FR 79797 through 79826; 82 FR 59445 through 59476; 83 FR 59110 through 59139; and 84 FR 61420 through 61434, respectively) for an overview of the regulatory history of the ASCQR Program. We have codified certain requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330). In this proposed rule, we propose to update certain currently codified program policies and propose a review and corrections period as well as other administrative changes. We discuss these proposals in more detail below in sections XV.C. and XV.D.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when such measures are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized, and codified at 42 CFR 416.320 an updated set of factors [100] and the process for removing measures from the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115) for a detailed discussion of our process regarding measure removal. We are not proposing any changes to the measure removal factors in this proposed rule.

3. Summary of ASCQR Program Quality Measure Set Previously Finalized for the CY 2024 Payment Determination and for Subsequent Years

We are not proposing to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. Table 45 summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

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TABLE 45: FINALIZED ASCQR PROGRAM MEASURE SET FOR THE CY 2024 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn*
ASC-2	0266†	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***
ASC-15e	None	OAS CAHPS – Recommendation of Facility***
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers****

† NQF endorsement was removed.
* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123).
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).
**** Measure will be added beginning with the CY 2024 payment determination as set forth in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61421 through 61428).

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4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012 through 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program, which are codified at 42 CFR 416.325. We are not proposing any changes to these policies.

5. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017 and 2018 OPPS/ASC final rules with comment period (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through

[100] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies.

6. ASCQR Program Measures and Topics for Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. We also seek measures that would facilitate meaningful comparisons between ASCs and hospitals. Therefore, we invite public comment on new measures for our consideration that address care quality in the ASC settings as well as on additional measures that could facilitate comparison of care provided in ASCs and hospitals.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding the maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i).

In this proposed rule, we propose to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' refers to ''the individual(s)'' who have responsibilities for security and account management requirements for a facility's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We also propose to revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official''. The new sentence would read: ''A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.'' We invite public comment on our proposals.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Update of Language Generally

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310. We currently use the phrases ''data collection period'' and ''data collection time period'' interchangeably in § 416.310(a) through (c). We believe that using one, consistent phrase will streamline and simplify the section and our policies to help avoid potential confusion. As such, we propose to remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, and replace it with the phrase ''data collection period''—specifically at § 416.310(a)(2), (b), (c)(1)(ii), and (c)(2), as well as replacing the phrase ''time period'' with ''period'' in § 416.310(c)(1)(ii) for language consistency. We invite comment on our proposal.

b. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2).

We are not proposing any changes to these requirements. We note that data submission for the following claims-based measures using QDCs was suspended in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123 and 83 FR 59134 through 59135) until further action in rulemaking:

- *ASC–1:* Patient Burn;
- *ASC–2:* Patient Fall;
- *ASC–3:* Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- *ASC–4:* Hospital Transfer/Admission.

Furthermore, we note that the previously finalized data processing and collection period requirements will apply to any future claims-based -measures using QDCs adopted in the ASCQR Program.

c. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We are not proposing any changes to these policies.

As noted above, while data submission for certain claims-based measures using QDCs was suspended, our policies for minimum threshold, minimum case volume, and data completeness requirements will apply to any future claims-based measures using QDCs adopted in the ASCQR Program.

d. Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138), for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously finalized measures:

- *ASC–12:* Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
- *ASC–19:* Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We are not proposing any changes to the requirements for non-QDC based, claims-based measures.

e. Requirements for Data Submitted via an Online Data Submission Tool

(1) Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool: *https://www.qualitynet.org.* We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i).

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- *ASC–9:* Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- *ASC–11:* Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery
- *ASC–13:* Normothermia Outcome
- *ASC–14:* Unplanned Anterior Vitrectomy

We are not proposing any changes to these policies for data submitted via a CMS online data submission tool.

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (that is, the CDC NHSN website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2).

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59135), no measures submitted via a non-CMS online data submission tool remain in the ASCQR Program beginning with the CY 2020 payment determination. We are not proposing any changes to our non-CMS online data submission tool reporting requirements; these requirements would apply to any future non-CMS online data submission tool measures adopted in the ASCQR Program.

f. Requirements for Data Submission for ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified these policies at 42 CFR 416.310(e). However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), we delayed implementation of the ASC15a–e: OAS CAHPS—Survey-based -measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking, and we refer readers to that discussion for more details. We are not proposing any changes to this policy.

g. ASCQR Program Data Submission Deadlines

While the ASCQR Program has established submission deadlines (42 CFR 416.310), there is no specified policy for deadlines falling on nonwork days. Therefore, we propose that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' Specifically, the Act indicates that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day, all or part of which is declared to be a nonwork day for federal employees by statute or Executive order, shall be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order (42 U.S.C. 416(j)). Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the ASCQR Program is administered. As such, we propose to add this policy for the submission deadlines associated with the ASCQR Program beginning with the effective date of this rule. We also propose to codify this policy by adding a new paragraph (f) at § 416.310, which would read ''All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.'' We invite public comment on our proposals.

2. Proposed Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool in the ASCQR Program

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[101] For example, ASCs collect measure data from January 1, 2019 through December 31, 2019 and submit these data to CMS from January 1, 2020 through May 15, 2020. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In this proposed rule, we propose to formalize that process and create a review and corrections period similar to that being proposed for the Hospital OQR Program in section XIV.D.7 of this proposed rule. For the ASCQR Program, we propose to implement a review and corrections period which would run concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs could enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. We also propose to codify this review and corrections period at new paragraph (c)(1)(iii) in § 416.310, which would read ''For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.'' We invite public comment

[101] ASCQR Program Data Submission Deadlines. Available at: *https://www.qualitynet.org/asc/data-submission#tab2.*

on our proposals, including on the burden and benefits of such a review and corrections period.

3. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We are not proposing any changes to this policy.

4. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) Changed the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018; and (2) revised 42 CFR 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We are not proposing any changes to these policies.

E. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2021, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted hospital market basket update factor. The MFP adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and

appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2020 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for CY 2021.

XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

A. Background

The Overall Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs, in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars. The Overall Star Rating was first introduced and reported on *Hospital Compare* in July 2016 [102] and has been refreshed six times,[103] [104] [105] [106] two of which included minor methodology updates,[107] [108] over the past years. *Hospital Compare,* and any successor site, is a public website hosted by CMS with transparent information and data on over 100 quality measure for over 4,000 hospitals, nationwide in the United States, for consumers and researchers. In this rule, for the Overall Star Ratings, the term ''publish'' refers to the public posting of the Overall Star Rating and ''refresh'' refers to the public posting quality measure and program data on *Hospital Compare* or its successor website.

During development of the Overall Star Rating, we established guiding principles to use methods that were scientifically valid, inclusive of hospitals and measure information, accounted for the heterogeneity of available measures and hospital reporting, and accommodated changes in the underlying measures.[109] In addition, we aimed to provide alignment with the information displayed on *Hospital Compare* and the measures and methods used within CMS programs, transparency of Overall Star Rating methods, and responsiveness to stakeholder input. After the launch of the Overall Star Rating in July 2016 and as the Overall Star Rating gained broader use by multiple stakeholders, we added new guiding principles to guide reevaluation of the methodology.[110]

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose a methodology which includes elements of the current methodology as well as updates (we refer readers to section E. Current and Proposed Overall Star Rating Methodology) that aim to increase simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We are also proposing to include Veterans Health Administration (VHA) hospitals (we refer readers to section C. Veterans Health Administration Hospitals in Overall Star Rating) and Critical Access Hospitals (CAHs) (we refer readers to B. Critical Access Hospitals in the Overall Star Rating) in the Overall Star Rating. In addition, we propose to establish the Overall Hospital Quality Star Rating and methodology at subpart J of part 412 (proposed § 412.190).

Because of our production timeline to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of public release, we are using this CY 2021 OPPS/ASC proposed rule to propose the methodology for the Overall Star Rating even though it includes not only hospital outpatient measures, but also hospital inpatient measures, which are generally discussed in the Inpatient Prospective Payment System (IPPS) rule. We plan to reference policies for the Overall Star Rating in the FY 2022 IPPS rule.

1. Purpose, Authority, and Applicable Hospital Quality Data

a. Purpose

In 2014, to inform the initial methodology for the Overall Star Rating, we conducted a review of the literature as well as a review of prior and current star rating efforts. This review supported the notion that patients care about information on hospital quality, but that patient use of this information is limited by low understanding of quality information. Additionally, we heard feedback that hospital quality information is often intimidating as displayed and is not user-friendly in comparison to other consumer ratings. The key findings of the review were consistent with consumer priorities to bring a wide variety of measures together into a single overall star rating. Therefore, we sought to help consumers understand hospital quality information through development of a summary measure, which combines publicly reported quality information in an easy-to-understand rating that is familiar to consumers.

The primary objective of the Overall Star Rating was to use an established, evidence-based statistical approach to summarize hospital quality measure

[102] Centers for Medicare & Medicaid Services. (2016, July 27). *First Release of the Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from *www.cms.gov/newsroom: https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare.*

[103] Centers for Medicare & Medicaid Services. (2016, May). *Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.*

[104] Centers for Medicare & Medicaid Services. (2016, October). *Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.*

[105] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.*

[106] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[107] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[108] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[109] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[110] Ibid.

results reported on *Hospital Compare* with the goal of assigning acute care hospitals and facilities that provide acute inpatient and outpatient care in the U.S. to an overall rating between one and five whole stars.[111] The Overall Star Rating is meant to complement other hospital quality information publicly posted on *Hospital Compare* or its successor website, including the individual measure scores and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Star Rating.[112] The original guiding principles of the Overall Star Rating was to use scientifically valid methods that are inclusive of hospitals and measure information, able to account for different hospitals reporting on different measures, and able to accommodate changes in the underlying measures over time.[113] We also aimed to create alignment with *Hospital Compare* and CMS programs, transparency of the methods for calculating the Overall Star Rating, and responsiveness to stakeholder input through various and ongoing engagement activities.

The goal of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. To this end, we propose that (1) the Overall Star Rating is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals, (2) the guiding principles of the Overall Star Rating are to use scientifically valid methods, inclusive of hospitals and measure information and able to accommodate measure changes; alignment with *Hospital Compare* or its successor website and CMS programs; provide transparency of the methods for calculating the Overall Star Ratings; and be responsive to stakeholder input; and (3) and to codify this at § 412.190.

b. Subsection (d) Hospitals

The Overall Star Rating includes measures that (1) capture quality of care at hospitals and facilities providing acute inpatient and outpatient care and (2) are publicly reported on *Hospital Compare* or its successor websites. CMS currently publicly reports information regarding the performance of individual hospitals in the following CMS quality programs: Hospital Inpatient Quality Reporting (IQR) Program, Hospital Readmission Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, Hospital Value-Based Purchasing (VBP) Program, and Hospital Outpatient Quality Reporting (OQR) Program. Such authority is granted under applicable sections 1833 and 1886 of the Act.[114]

Specifically, under sections 1886(b)(3)(B)(viii)(VII) and 1833(t)(17)(E) of the Act for the Hospital IQR and OQR Programs respectively, the Secretary is required to make quality information available to the public. Section 1886(b)(3)(B)(viii)(VII) of the Act states that ''The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to furnished in inpatient settings in on the internet website of the Centers for Medicare & Medicaid Services.'' Section 1833(t)(17)(E) of the Act states that ''The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the internet website of the Centers for Medicare and Medicaid Services.'' We believe that these requirements allow the agency to create the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the Hospital IQR and OQR Programs, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

In addition, the HRRP (under section 1886(q)(6)(A) of the Act) and the HAC Reduction Program (under section 1886(p)(6)(A) of the Act) require that the Secretary must make information regarding readmission and hospital acquired condition rates for hospitals available to the public. Specifically, section 1886(q)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program'' and section 1886(p)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.'' Similar to Hospital IQR and OQR Programs, we believe that these requirements allow the agency to create and publicly release the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the HRRP and HAC Reduction Program, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

Our use of data reported by hospitals under the Hospital VBP Program in the Overall Star Ratings is supported by section 1886(o)(10)(A)(i) of the Act. Specifically, section 1886(o)(10)(A) of the Act states that ''The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including (i) the performance of the hospital with respect to each measure that applies to the hospital; (ii) the performance of the hospital with respect to each condition or procedure; and (iii) the hospital performance score assessing the total performance of the hospital.'' Hospitals that participate in the Hospital VBP Program report data on each Hospital VBP measure for a specified performance period that applies to the program year. Under our proposed star rating methodology, which we describe in detail below, we would use these Hospital VBP measure rates, in combination with measure rates reported by various hospitals under the Hospital IQR Program, Hospital OQR Program, HRRP, and HAC Reduction Program to calculate and make public a star rating that applies to the hospital for a corresponding star rating period, making that star reflective of the hospital's measured level of quality in all of these programs.

[111] Centers for Medicare and& Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[112] Centers for Medicare and& Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[113] Centers for Medicare and& Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[114] U.S. Congress. (1934) *United States Code: Social Security Act, 18 U.S.C. 1833 and 1886.*

The Overall Star Ratings does not use data reported by hospitals under the Prospective Payment System-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, the Inpatient Psychiatric Facilities (IPF) Quality Reporting Program, or the Ambulatory Surgical Centers (ASC) Quality Reporting Program.

Beginning with publication of Overall Star Rating in CY 2021 and subsequent years, we propose to: (1) Continue to use data publicly reported on a CMS website from the programs described above as a basis to calculate the Overall Star Ratings, and (2) codify this at § 412.190. We invite public comment on our proposals.

B. Critical Access Hospitals in the Overall Star Rating

1. Current Critical Access Hospitals in the Overall Star Rating

The current Overall Star Rating is calculated based on certain data that is publicly reported on a CMS website and includes data from hospitals and facilitates that provide acute inpatient and outpatient care, including critical access hospitals (CAHs). Many CAHs currently voluntarily submit measure data consistent with certain CMS quality programs and elect to have their quality measure data publicly reported through their QualityNet account by selecting Optional Public Reporting Notice of Participation. We note, however, that the Hospital OQR Program no longer uses a Notice of Participation form (83 FR 59103 through 59104). Submission of data through the Hospital OQR Program is considered participation specifically in that program. If a CAH elects to voluntarily submit data and have their quality measure data publicly reported, they are subsequently eligible to receive a star rating so long as they meet the specified reporting thresholds, discussed in detail in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating.

We note that many CAHs do not meet the minimum threshold to receive a star rating due to serving too few patients to report some of the underlying measures. To date, typically anywhere from 48 to 55 percent of CAHs report enough measures to receive a star rating.

2. Proposal To Continue To Include Critical Access Hospitals in the Overall Star Rating

In this proposed rule, the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating through authority in section 1704 of the Public Health Service Act (PHSA).[115] Section 1704 of the PHSA states that ''The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters.'' We believe that this authority allows the agency to include CAHs in Overall Star Rating because the purpose of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make informed decisions about their healthcare. We have an existing contract mechanism through our current Healthcare Quality Analytics and Reports (HCQAR) contract, which would continue under a future similar contract vehicle as appropriate, for the calculation of the Overall Star Rating for all hospitals that provide acute inpatient and outpatient care, including CAHs, and for the dissemination of reports to these hospitals prior to public release. Any hospital or facility providing acute inpatient and outpatient care, including CAHs, with measure or measure group scores reported on *Hospital Compare* or its successor website are given a confidential hospital-specific report (HSR) during the Overall Star Rating preview where they may review their measure, measure group, and star rating results prior to public release. The Overall Star Rating preview period and confidential hospital-specific reports are discussed in more detail in section F. Preview Period.

In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[116] Many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[117] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to include as much information as possible about hospital quality. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs.

Therefore, we propose that CAHs that wish to be voluntarily included in the Overall Star Rating must have elected to both (a.) voluntarily submit quality measures included in and as specified by CMS hospital programs and (b.) publicly report their quality measure data on one of CMS' public websites. We propose to codify this at § 412.190. CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation. Since CAHs voluntarily report measures, CAHs may have their Overall Star Rating withheld from public release provided they submit a timely request, as described in more detail under section G. Overall Star Rating Suppressions.

Of note, the proposal to peer group hospitals by the number of measure groups, as outlined in section E.7. Proposed Approach to Peer Grouping Hospitals, is dependent on CAH participation in the Overall Star Rating since CAHs make up approximately half of the hospitals within the three measure peer group and excluding CAHs from the Overall Star Rating would not provide a sufficient amount of hospitals to make peer group comparisons.

We invite public comment on our proposals to include CAHs in the Overall Star Rating, the processes for CAHs to (a.) voluntarily submit quality measures included in CMS hospital programs and (b.) publicly report their quality measure data on one of CMS' public websites, and to codify this at

[115] Public Health Service Act of 2019, Public Law 116–69, Page 133 STAT. 1134, codified as amended at 42 U.S.C. 201.

[116] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[117] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.*

§ 412.190. We note that for the purposes of the rest of this discussion, we will refer to both subsection (d) hospitals and CAHs as ''hospitals.''

C. Veterans Health Administration Hospitals in the Overall Star Rating

In this proposed rule, we propose to include quality measure data from Veterans Health Administration hospitals (VHA hospitals) for the purpose of calculating Overall Star Rating beginning with the CY 2023. CMS has an existing contract mechanism with the Veterans Health Administration (VHA) through an Interagency Agreement to publish their hospitals' quality measure data on *Hospital Compare* [118] in accordance with section 206(c) of the Veterans Access, Choice, and Accountability Act (Choice Act) of 2014 (Pub. L. 113–146).[119]

Furthermore, section 1704 of the PHSA [120] allows the Secretary to make health information available to consumers of medical care through grant or contract mechanism including, but not limited to, the publication of health information. In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[121] We believe this includes the publication of quality measure data and Overall Star Rating for VHA hospitals.

Therefore, in this proposed rule, we propose to include VHA hospitals in the Overall Star Rating beginning in CY 2023. Including VHA hospitals in the Overall Star Rating beginning in CY 2023 allows CMS to establish the methodology through this proposed rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. In order to be eligible to receive a star rating, VHA data would be subject to the same reporting threshold as subsection (d) hospitals and CAHs included in the Overall Star Rating (proposed as three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating).

We anticipate that adding VHA hospital data to the Overall Star Rating calculation would influence national results due to several steps in the Overall Star Rating methodology that inherently assess quality measure performance in a relative manner, or by comparing hospitals to other hospitals. This influence is present in three places of the Overall Star Rating methodology: In the standardization of individual measure scores, in the standardization of measure group scores, and in the calculation of star ratings using k-means clustering. The addition of VHA hospitals has no direct influence on CMS-administered programs, however. CMS program impacts, including payment and burden, are assessed based on hospitals participating in CMS' programs and do not include VHA hospitals in those determinations. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule.

We invite public comment on our proposal to include VHA hospitals in the Overall Star Rating beginning with CY 2023.

D. History of the Overall Hospital Quality Star Rating

Prior to introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, we engaged stakeholders throughout development of the methodology. CMS' Overall Star Rating development contractor convened both a Technical Expert Panel (TEP), consisting of national statistical experts, providers, purchasers, and patient advocates, and a Patient & Advocate Work Group, as well as hosted two public input periods [122] [123] to gain stakeholder feedback on aspects of the methodology. Specifically, feedback was solicited on topics such as measure inclusion and groupings, statistical and non-statistical approaches to summarizing measures, weightings for individual measures and measure groups, and approaches to classifying hospitals to star ratings. In 2015, we hosted a confidential hospital dry run to provide all hospitals and facilities that provide acute inpatient and outpatient care with a private report on their measure performance, measure group scores, and star ratings results, which allowed hospitals to preview their preliminary results without public posting and to familiarize themselves with the methodology.[124] Concurrent with the July 2016 preview period, we also hosted a national provider call to present the final methodology and answer stakeholder questions.[125]

For the initial July 2016 and each subsequent release of the Overall Star Rating, including October 2016, December 2016, December 2017, February 2019, and January 2020, we have continuously provided resources to maintain transparency and facilitate understanding of the methods, including three National Provider Calls [126] [127] [128] as well as methodology reports,[129] hospital-specific reports,[130] and open access datasets with quality measure data used to calculate the Overall Star Rating (referred to as the public input file), and SAS programing code used to calculate the Overall Star Rating along with supporting documents to allow stakeholders to understand and replicate the Overall Star Rating results.

Since the introduction of the Overall Star Rating on the *Hospital Compare*

[118] Centers for Medicare & Medicaid Services. (2016, October 19). *Veterans Health Administration Hospital Performance Data.* Retrieved July 6, 2020, from *www.cms.gov; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/VA-Data.*

[119] Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146, Page 128 STAT. 1754, codified as amended at 38 U.S.C. 1703C(b)(1).

[120] Public Health Service Act of 2019, Public Law 116–69, Page 133 STAT. 1134, codified as amended at 42 U.S.C. 201.

[121] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[122] Centers for Medicare & Medicaid Services. (2015, January). *Hospital Compare Star Ratings Public Comment Report 1: Measure Selection for Hospital Star Ratings.*

[123] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[124] Centers for Medicare & Medicaid Services. (2018, September 18). *Hospital Compare Overall Star Ratings Dry Run Q&A.* Retrieved from *www.qualitynet.org: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab4.*

[125] Centers for Medicare & Medicaid Services. (2015, August 13). *Centers for Medicare & Medicaid Services Hospital Compare Overall Star Ratings Methodology MLN Connects National Provider Call.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-08-13-Star-Ratings.*

[126] Ibid.

[127] Centers for Medicare & Medicaid Services. (2016, May 12). *Centers for Medicare & Medicaid Services Overall Hospital Quality Star Ratings on Hospital Compare National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event134/.*

[128] Centers for Medicare & Medicaid Services. (2017, November 30). *Centers for Medicare & Medicaid Services Hospital Quality Star Ratings on Hospital Compare December 2017 Methodology Enhancements National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event107/.*

[129] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[130] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

website in July 2016, the Overall Star Rating development contractor has continued to engage stakeholders by convening two additional TEPs, maintaining the Patient & Advocate Work Group, convening a new Provider Leadership Work Group, consisting of hospital quality and medical staff, and hosting two additional public input periods.[131] [132] As a result of ongoing reevaluation and stakeholder engagement, we updated the methodology in December 2017 and February 2019. CMS also hosted a National Provider Call [133] to facilitate the December 2017 methodology enhancements and nine listening sessions to facilitate the February 2019 methodology enhancements. The current methodology includes enhancements made in December 2017 [134] and February 2019.[135]

1. Reevaluation of the Overall Hospital Quality Star Rating Methodology

The Overall Star Rating is a summary of certain existing hospital quality information, which is collected and reported as part of several CMS programs to improve and make transparent the quality of care provided at hospitals that provide acute inpatient and outpatient care. As the underlying measures reported on *Hospital Compare* have been added, updated, and removed, and as stakeholders have begun using the methodology for purposes beyond consumer transparency, including provider quality improvement efforts, we propose refinements to the methodology of the Overall Star Rating. Since the first reporting of the Overall Star Rating in July 2016, we have maintained an active monitoring and re-evaluation process for the methodology, as well as engaged stakeholders for continuous feedback. Based on this ongoing reevaluation work, we have released multiple, iterative updates to the methodology in December 2017 [136] and February 2019 [137] that addressed stakeholder concerns revealed through previous stakeholder engagement by the TEP [138] [139] and during public input. We refer readers to section E.4.a.(2) Latent Variable Modeling Measure Loadings for an overview of the February 2019 methodology updates.

Between 2018 and 2019, CMS' Overall Star Rating development contractor received input on several potential methodology updates through two TEP meetings,[140] three Patient & Advocate Work Group meetings, two Provider Leadership Work Group meetings, nine public listening sessions,[141] and one public input period.[142] Through these reevaluation analyses and stakeholder engagement, we identified three aforementioned overarching areas of improvement for the Overall Star Rating methodology—simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals that provide acute inpatient and outpatient care.[143] [144] Simplicity of the methodology means we aim to reduce the statistical complexity of the methodology, while maintaining a representative summary of hospital quality data, so that stakeholders can better understand how the Overall Star Rating is calculated. Predictability of measure emphasis within the methodology over time means we aim to create a methodology that assigns similar measure weight, or emphasis, to each measure to calculate measure group scores and Overall Star Rating over time (each Overall Star Rating publication). Comparability of ratings among hospitals means we aim to create a methodology that compares hospitals that are more similar to each other, such as the measures they report or services they provide, when calculating the Overall Star Rating.

Since the original introduction of the Overall Star Rating, stakeholders have requested a less complex, or simplified, methodology so that providers can better understand the methodology, interpret their star rating, and use the Overall Star Rating to identify areas for quality improvement.[145] We developed the current methodology under the original principles of the Overall Star Rating, which was to use a statistical approach to summarize quality measures for patients.[146] The current methodology aims to prioritize patient usability and employs data-driven statistical modeling approaches, including latent variable modeling [147] and k-means clustering,[148] to calculate measure group scores and to assign hospital summary scores to star ratings. In summary, the current methodology is designed to rely on data for several

[131] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[132] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[133] Centers for Medicare & Medicaid Services. *Overall Hosptial Quality Star Ratings on Hospital Compare.* (2016, 12 May). Retrieved from *www.qualityreportingcenter.com: https://www.qualityreportingcenter.com/globalassets/migrated-pdf/iqr_20160512_npc-overall-star-rating_vfinal5.9.16.508.pdf.*

[134] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[135] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[136] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[137] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[138] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[139] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[140] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[141] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[142] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[143] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[144] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[145] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[146] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[147] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[148] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

critical steps in the star ratings calculation. A couple of the proposed methodology updates aim to increase the simplicity of the methodology for health care providers seeking to replicate, better understand, or communicate an interpretation of the Overall Star Rating,—including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative discussed below in section E.3.b.(2) Proposed New Measure Group: Timely and Effective Care and (2) using a simple average of measure scores to calculate measure group scores discussed below in section E.4. Step 3: Calculation of Measure Group Scores.

Several proposed refinements aim to address the predictability of measure emphasis within the methodology over time. Between the December 2017 and the intended July 2018 publication of the Overall Star Rating, there were no Overall Star Rating methodology updates; however, there were several measure-level updates, including the introduction of two new measures (Severe Sepsis and Septic Shock: Early Management Bundle and Pneumonia Excess Days in Acute Care), the removal of one measure (Pneumonia 30-day Readmission), and updated specifications for the CMS Patient Safety Indicator Composite (CMS PSI–90) measure.[149] The updates to the underlying measures for the July 2018 confidential preview period resulted in differences in the emphasis of measure contributions to the star rating calculation from previous releases.[150] These observed changes in star ratings were similar to star rating shifts observed between reporting periods for other CMS star rating programs, however greater than the shifts observed in prior Overall Star Rating publications. While some shifts in star ratings are expected as hospital performance worsens or improves relative to other hospitals in the nation and as measures are added, updated, and removed from the Overall Star Rating calculation, results from the July 2018 confidential preview period illuminated the extent of the sensitivity of a data-driven statistical model to underlying measure updates. As a result of this unexpected change in measure emphasis, we did not move forward with public release of the July 2018 Overall Star Rating and instead focused on potential improvements to the methodology and stakeholder engagement. Several of the proposed methodology updates, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative, discussed below in section E.3. Step 2: Assignment of Measures to Groups; (2) use of a simple average of measure scores to calculate measure group scores, discussed below in section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores; and (3) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating, aim to address concerns around the predictability of measure emphasis, and in turn star ratings, over time.

Comparability of the Overall Star Rating is a commonly expressed priority by stakeholders.[151] [152] Hospitals that provide acute inpatient and outpatient care differ in size or patient volume, geographical location, urban or rural location, patient populations treated, and services offered. In turn, hospitals differ in the number and type of quality measures reported. All hospitals providing acute inpatient and outpatient care, regardless of differences in any of these characteristics, are included within the Overall Star Rating calculation and are eligible to receive a star rating. Stakeholders, primarily providers on the TEP, Provider Leadership Work Group, and during a public input period, have highly recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability of hospital star ratings.[153] [154] Several of the proposed methodology updates, including (1) stratifying the Readmission measure group according to proportion of dual-eligible patients at each hospital; (2) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and (3) peer grouping hospitals by number of measure groups, discussed below in section E.7. Proposed Approach to Peer Grouping Hospitals, aim to increase the comparability of hospitals for patients and providers.

In 2019, we conducted extensive analyses and engaged multiple stakeholder groups to evaluate each of the proposed methodology updates outlined below. Most notably, CMS' Overall Star Rating development contractor recruited and convened a third TEP to provide technical input,[155] a second Provider Leadership Work Group to provide policy input, and a second Patient & Advocate Work Group to provide input on usability, and we hosted a public listening session,[156] all to gain a range of new perspectives on the current methodology and potential methodology updates.

E. Current and Proposed Overall Star Rating Methodology

1. Overview

The current Overall Star Rating methodology can be outlined within six steps briefly described here and in more detail further below. In the first step, the measures are selected from among those reported on *Hospital Compare* to include as much information as possible while considering whether the measures are suitable for combination within the Overall Star Rating. In the first step, the measure scores are also standardized to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. In the second step, the measures are grouped into one of seven measure groups. Third, for each group, a statistical model, called a latent

[149] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

[150] Centers for Medicare & Medicaid Services. (2018, May). Quarterly Updates and Specifications Report: July 2018. Retrieved from: *https://www.qualitynet.org/files/5d0d3abf764be766b0104a21?filename=StarRatingsJul18_UpdtSpecsRpt.pdf.*

[151] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[152] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[153] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[154] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[155] Ibid.

[156] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

variable model (LVM), is used to determine a group score for each hospital reporting on measures in that group. In the fourth step, a weight is applied to each measure group score and all available measure groups are averaged to calculate the hospital summary score. In the fifth step, hospitals that provide acute inpatient and outpatient care reporting too few measures and measure groups are excluded. Finally, hospital summary scores are organized into five categories, representing the five star ratings, using an algorithm process called k-means clustering. K-means clustering is a method to cluster data so that observations within one cluster are more similar to each other than observations in another cluster.[157]

In this proposed rule, for public release of the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to both retain and update certain aspects of the current Overall Star Rating methodology, as outlined below within each of the six steps of the current methodology. Generally, we propose to retain the following aspects of the current Overall Star Rating methodology:

- An annual publication cycle using data posted on *Hospital Compare* or its successor site from data publicly reported within the prior year; for example, the Overall Star Ratings published in January 2020 used data publicly reported from the October 2019 refresh;
- Suppression policy for subsection (d) hospitals;
- Inclusion of measures publicly reported on *Hospital Compare* or its successor sites that meet specific inclusion and exclusion criteria and standardization of measure score within Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating;
- Publicly displaying measure group level information for measure groups for which a hospital has at least three measures, use of weighted average of measure group scores to calculate summary scores and measure group reweighting to account for measure group scores which are not reported within Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores; and
- Use of k-means clustering to assign hospitals that provide acute inpatient and outpatient care to one of five star ratings within Step 6: Application of Clustering Algorithm to Obtain a Star Rating.

We propose to make the following methodology updates:

- Regroup measures as a result of the Meaningful Measure Initiative (83 FR 41147 through 41148) by combining the three process measure groups into one group, Timely and Effective Care, within Step 2: Assignment of Measures to Groups;
- Update the calculation of measure group scores to include standardization of measure group scores and to use a simple average of measure scores, rather than latent variable modeling;
- Stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3: Calculation of Measure Group Scores;
- Change the reporting thresholds to receive a star rating to three measures within three measure groups, one of which must be Mortality or Safety of Care, within Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and
- Apply peer grouping of hospitals that provide acute inpatient and outpatient care based on number of measure groups between Step 5: Application of Minimum Thresholds for Receiving a Star Rating and Step 6: Application of Clustering Algorithm to Obtain a Star Rating. These are discussed in more detail in section E.7. Proposed Approach to Peer Grouping Hospitals.

2. Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

a. Timeframe

(1) Current Timeframe

Generally, for CMS quality programs, we update measure data results on the *Hospital Compare* or its successor website quarterly in January, April, July, and October of each year. In the past, the Overall Star Rating was published on *Hospital Compare* both quarterly and biannually. Beginning in February 2019, the Overall Star Rating was published annually. In January 2020, the Overall Star Rating continued the annual publication cycle with the additional approach of using data publicly posted on *Hospital Compare* in a quarter prior to the update to calculate star ratings. For example, we used October 2019 publicly reported measure data on *Hospital Compare* to calculate Overall Star Rating results for the January 2020 publication.[158] Note that the data collection period for each measure varies depending on measure specifications that set minimum case requirements to ensure individual measure reliability and meet the requirements of CMS quality programs, as detailed in each program's respective rules as well as on *Hospital Compare* or its successor website.

(2) Proposal To Retain Current Timeframe With Modification

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to retain the current timeframe with modification, such that the Overall Star Rating would continue to be published once annually; however, instead of using data from the same quarter as or the quarter prior to the publication of the Overall Star Rating, we would use publicly available measure results on *Hospital Compare* or successor website from a quarter within the prior year. As mentioned above, for CMS quality programs, we generally update measure data results on the *Hospital Compare* or its successor website quarterly in January, April, July, and October of each year. Therefore, we would use publically reported data from one of those four *Hospital Compare* refreshes to calculate the Overall Star Rating. For example, for a January 2021 Overall Star Rating release, we could use data refreshed on *Hospital Compare* in, July or October of 2020. We propose to codify this timeframe at § 412.190.

We believe publishing the Overall Star Rating once a year is appropriate because it may minimize period to period changes in hospital star ratings that may result from small changes in individual hospital and national performance for the underlying measures. Furthermore, publishing the Overall Star Ratings once a year would allow time for the star ratings to reflect improvements or updates in hospital performance on the underlying measures. It also is aligned with the current cycle of many underlying measures, particularly highly weighted outcome measures that are also refreshed annually. Also, using data publicly reported on *Hospital Compare* or its successor website within the prior year, rather than data publicly reported concurrent with the Overall Star Rating, would allow providers more time, beyond the standard 30 days, to review their star rating as well as the measure and measure group results that

[157] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[158] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

contribute to their star rating during the confidential preview period (we refer readers to section F. Preview Period). Hospitals that provide acute inpatient and outpatient care may use this additional time to more thoroughly anticipate and understand their results as well as generate communication or improvement strategies.

We invite public comment on our proposals to: (1) Publish the Overall Star Rating once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year, and (2) codify this at § 412.190.

b. Measure Inclusion

(1) Current Measure Inclusion

Generally, measures publicly reported on *Hospital Compare* or its successor site through CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, were used to calculate Overall Star Rating. We did not include publicly reported measures from any CMS programs not measuring acute inpatient or outpatient care or pertaining to specialty hospitals, such as cancer hospitals, and ambulatory surgical centers, such as the PPS-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, or Ambulatory Surgical Centers Quality Reporting (ASCQR). The goal of Overall Star Rating is to summarize quality of care at hospitals providing acute inpatient and outpatient care and thus, only include measure scores representing quality of acute inpatient and outpatient care.

Any measures that were removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor website were not included.

(2) Proposal To Retain Current Measure Inclusion

In this proposed rule, we propose to continue the same practice by incorporating measures summarizing quality of care at inpatient and outpatient care hospitals in the Overall Star Rating. Specifically, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to use certain measures publicly reported on the *Hospital Compare* or successor website through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, to calculate the Overall Star Rating. We also propose to codify this policy at § 412.190.

We believe hospital inpatient and outpatient measures publicly reported on *Hospital Compare* or its successor website are appropriate for the Overall Star Rating because they capture the quality of care at hospitals providing acute inpatient and outpatient care and provide a snapshot of quality when combined together. We recognize that measures reported on *Hospital Compare* or its successor website undergo a rigorous development process which includes extensive measure testing, vetting by stakeholders, evaluation by the National Quality Forum, and undergo rulemaking for inclusion in CMS programs and public reporting. We have not and do not intend to make any changes to the underlying measures or measure scores specifically for the calculation of the Overall Star Rating. As such, the Overall Star Rating methodology uses the measures as specified under the CMS programs, and measure scores as reported on *Hospital Compare* or its successor website at the time of the Overall Star Rating calculation. As noted above, any measures that are removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor website are not included. Additional measure exclusions are discussed in the next section. Also, we refer readers to sections B. Critical Access Hospitals in the Overall Star Rating and C. Veterans Health Administration Hospitals in Overall Star Rating for our discussions about CAHs and VHA hospitals.

We invite public comment on our proposals: (1) Use measures publicly reported on *Hospital Compare* or its successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Programs, for the Overall Star Rating in CY 2021 and subsequent years, and (2) codify this policy at § 412.190.

c. Measure Exclusions

(1) Current Measure Exclusions

Of the measures publicly reported on the *Hospital Compare* website through the CMS quality programs listed in a previous section, in the past, we have excluded some measures from the Overall Star Rating methodology for various reasons. The measures excluded fall into the following categories:

1. Measures with no more than 100 hospitals reporting performance publicly, as these measures would not produce reliable measure group scores based on so few hospitals;

2. Structural measures not amenable to inclusion in a summary scoring calculation alongside process and outcome measures, as these measures cannot be as easily combined with other measures captured on a continuous scale with more granular data;

3. Non-directional measures (for which it is unclear whether a higher or lower score is better, such as payment measures), as these measures cannot be standardized to form an aggregate measure group score;

4. Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs, that is the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program and Hospital VBP Program, due to the purpose of Overall Star Rating being a summary of measure information as displayed on *Hospital Compare* or its successor websites;

5. Overlapping measures (for example, measures that are identical to another measure, measures with substantial overlap in cohort and/or outcome, and measures that are part of an already-included composite measure), in order to avoid duplicative measure results within the methodology; and

6. Measures with statistically significant negative loadings estimated by the LVM as described further in section E.4.a.(2) Latent Variable Model Measure Loadings.

In February 2019, we excluded measures for which the LVM estimates as statistically significant negative loading, which indicated the measure had an inverse relationship with other measures in the group.[159] LVM is the a statistical method for combining information that represents a latent trait, in this case measures within a measure group that represent an aspect of hospital quality, to estimate a numerical score, in this case measure group scores.[160] Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[161] Latent variable modeling and measure loadings are described in more detail under section E.4. Step 3: Calculation of Measure Group Scores below.

[159] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[160] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[161] Ibid.

(2) Proposal To Retain and Update Select Measure Exclusions

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we intend to continue to exclude certain measures used to calculate the Overall Star Rating. We believe these measure exclusions remain appropriate moving forward because the Overall Star Rating is a summary of the existing publicly reported measures of hospital quality of care but not all measure scores can be reliably or appropriately combined with other measure scores. These are discussed in more detail below.

1. We propose to continue to exclude measures that only 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals.;

2. We propose to continue to exclude measures that are not able to be standardized and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.;

3. We propose to continue to exclude non-directional measures for which it is unclear whether a high or lower score is better. Without directional scores these measures cannot be standardized to be combined with other measures and form an aggregate measure group score as detailed in section E.2.d Measure Score Standardization.;

4. We propose to continue to exclude measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs.; and

5. We propose to continue to exclude measures that overlap with another measure in terms of cohort or outcome; this includes component measures that are part of an already-included composite measure. This exclusion criterion avoids duplicative measure results within the Overall Star Rating methodology. In general, we would determine which measures to include or exclude based on the level of information provided by the measure. For example, we would include a composite measure, such as PSI–90, over the component measures, such as PSI–03. As another example, we would include the excess days in acute care (EDAC) measures over the readmission measures, because while both measure sets have the same cohort, the EDAC measures capture a broader outcome inclusive of emergency department visits and observation stays in addition to the unplanned readmissions captured by both measures.

We also propose to codify these exclusions at § 412.190. We note that we are not proposing to continue to exclude measures with statistically significant negative loadings estimated by the LVM. (Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[162] and are further discussed in section E.4.a.(2) Latent Variable Model Measure Loadings). This is because, in section E.4.b. of this proposed rule, we propose to calculate measure group scores using a simple average of measure scores, instead of latent variable modeling. Should that proposal be finalized, measure loadings would no longer be produced as a product of latent variable modeling and, therefore, the exclusion criteria of measures with statistically significant negative loadings would no longer be necessary. However, should that proposal not be finalized, we would continue using LVM to calculate measure group scores and exclude measures with statistically significant negative loadings as discussed in section E.4.a.(2) Latent Variable Modeling Measure Loadings. We invite public comment on our measure exclusion proposals.

d. Measure Score Standardization

(1) Current Measure Score Standardization

In the past, once the relevant measures were excluded, the remaining measures are standardized to a single, common scale to account for differences in measure score units, such as ratios or rates, and direction, specifically whether a higher or lower score indicates better quality.[163] It is necessary to standardize all measure scores to the same scale (that is, units and direction) for combination into and calculation of measure group scores. To standardize, we used a statistical technique to calculate Z-scores for each measure.[164] A Z-score is a standard deviation score, which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. In the Overall Star Rating, Z-scores were produced by subtracting the national mean measure score from each hospital's measure score and dividing by the standard deviation [165] across hospitals. Standard deviation is a number that measures how far data values are from their average.[166] See the measure score standardization example and table 46. In addition, we changed the direction of all measures that indicate better performance with a lower score so that they were reversed to uniformly indicate that a higher score indicates better performance for all the measures prior to combination with other measures to calculate measure group scores.

(2) Proposal To Retain Current Measure Score Standardization

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to standardize measure scores as it allows for measures, which are different in units and direction, to be combined into aggregate measure group scores. Specifically, we propose that once applicable measures are excluded, we would standardize the remaining measures by calculating Z-scores for each measure prior to being combined in an aggregate measure group score so that all measures are on a single, common scale. That is, we would subtract the national mean measure score from each hospital's measure score and divide the difference by the measure standard deviation in order to standardize measures. We also propose to codify this at § 412.190.

Example of Standardization of Measure Score

Standardized measures score (HAI–6)

$$= -(0.470 - 0.694)/0.49 = 0.46$$

[162] Ibid.

[163] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[164] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[165] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[166] Ibid.

TABLE 46: EXAMPLE OF STANDARDIZATION OF MEASURE SCORES WITHIN SAFETY OF CARE MEASURE GROUP

Measure Name	Measure Score	Measure National Mean Score	Measure Standard Deviation	Standardized Measure Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	2.66%	0.005	-1.13
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	0.736	0.66	-0.75
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.806	0.64	0.09
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	0.826	0.68	1.21
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.867	0.89	0.97
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.843	0.69	0.98
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.694	0.49	0.46
PSI-90 Complication/Patient Safety for Selected Indicators	0.999	0.996	0.18	0.02

We invite public comment on our proposal to standardize measure scores and codify this policy at § 412.190.

e. Measure Score Winsorization

(1) Current Measure Score Winsorization

In the past, to avoid extreme outlier performance that may be potentially inaccurate or pose technical challenges to statistical estimations, the standardized measure scores were Winsorized [167] at the 0.125th and 99.875th percentiles of a standard normal distribution so that all measure scores range from negative 3 to positive 3 (−3 to 3). Winsorization [168] is a common strategy used to set extreme outliers to a specified percentile of the data. This step was necessary in order to minimize the impact of extreme measure score outliers on the performance of the latent variable modeling (LVM) (we refer readers to section E.4.a.(1) Latent Variable Modeling Overview for details). We chose to Winsorize the 0.125th and 99.875th percentiles to minimize the number of scores requiring Winsorization, while also allowing the models to perform properly and produce results. This approach to measure inclusion and standardization within the Overall Star Rating has been vetted previously through the TEP,[169] [170] Patient & Advocate Work Group, and a public input period.[171]

(2) Elimination of Measure Score Winsorization Moving Forward

We refer readers to section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores of this discussion in this proposed rule, where moving forward, we propose to calculate measure group scores using a simple average of measure scores for the Overall Star Rating beginning in CY 2021 and subsequent years, instead of latent variable modeling, as was used in the past. Because Winsorization was only necessary to minimize the impact of extreme outliers prior to statistical modeling to ensure model stability, the absence of LVM would eliminate the need for Winsorization. Eliminating Winsorization would be consistent with the proposal to replace the LVM with a simple average of measure scores, would support the goal of refinements to simplify the methodology, and would retain the original, observed performance of outlier hospitals within

[167] Kwak, S.K., & Kim, J.H. (2017, July 27).''Statistical data preparation: management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[168] Ibid.

[169] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[170] Centers for Medicare & Medicaid Services. (2014, December). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[171] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

the calculations. However, should we not finalize our proposal to adopt the simple average of measure scores and retain LVM to calculate measure group scores, as discussed in section E.4.a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling, we would continue to Winsorize measure scores to minimize the impact of extreme outliers.

3. Step 2: Assignment of Measures to Groups

a. Past Assignment of Measures to Groups

In the past, we have grouped measures into one of seven measure groups: Mortality, Safety of Care, Readmission, Patient Experience, Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging. Measures were grouped this way to align with the Hospital VBP Program [172] and the previous display of *Hospital Compare,*[173] to clinically reflect shared components of hospital quality, allow for measures to be added or removed as they are added or removed from public reporting, and to be useful to patients in making healthcare decisions as communicated by the Patient & Advocate Work Group. Grouping measures is also consistent with other CMS star rating initiatives, including Nursing Home Compare Star Ratings,[174] Medicare Plan Finder Star Ratings,[175] and Dialysis Facility Compare.[176]

b. Proposed New Measure Group and Continuation of Certain Groups

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to consolidate the three process measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one process measure group: Timely and Effective Care. We also propose to retain the current structure of the Mortality, Safety of Care, and Readmission, and the Patient Experience measure groups. These are discussed in more detail below.

(1) Continuation of the Mortality, Safety of Care, Readmission, and Patient Experience Measure Groups.

The Mortality, Safety of Care, Readmission, and Patient Experience measure groups were used in the past as noted above. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups contain an adequate number of publicly reported measures to produce robust measure group scores, reflective of differences in hospital quality. These measure groups were not as affected as the process of care measure groups, discussed in the next section, by the Meaningful Measure Initiative (83 FR 41147 through 41148).[177] In this proposed rule, for the Overall Star Rating beginning CY 2021 and subsequent years, we propose to continue to use these measure groups. We also propose to codify these measure groups at § 412.190.

(2) Proposed New Measure Group: Timely and Effective Care

Since the first release of the Overall Star Rating, measures have been: (1) Developed and adopted in CMS programs to address measurement gaps, and also (2) removed as a result of the Meaningful Measures Initiative (83 FR 41147 through 41148).[178] However, there has been a steady overall reduction in both the number of measures in CMS quality programs, as well as the number of measures publicly reported and available for inclusion in the Overall Star Rating—from 64 measures in the first publication of Overall Star Rating in 2016, to 51 measures for the most recent January 2020 publication.

More specifically, as finalized in the CY 2018 [179] and CY 2019 OPPS/ASC [180] final rules, and the FY 2019 IPPS/LTCH PPS final rule,[181] resulting from the Meaningful Measure Initiative (83 FR 41147 through 41148),[182] the following 12 process measures have been removed from the Hospital IQR and Hospital OQR Programs, and therefore, also from public reporting and the Overall Star Rating process measure groups between CY 2019 and CY 2021.

From the Effectiveness of Care measure group:

- Influenza Immunization (IMM–2) (83 FR 41151),
- Influenza Vaccination Coverage Among Healthcare Personnel (OP–27) (83 FR 37179 through 37186),
- Aspirin at Arrival (OP–4) (82 FR 59430),
- Colonoscopy Interval for Patients with a History of Adenomatous Polyps (OP–30) (83 FR 37179 through 37186), and
- Incidence of potentially preventable VTE (VTE–6) (83 FR 41151).

From the Timeliness of Care measure group:

- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1b) (83 FR 41151),
- Median Time to ECG (OP–5) (83 FR 37179 through 37186),
- Door to Diagnosis Evaluation by a Qualified Medical Professional (OP–20) (82 FR 59430),
- Median Time to Pain Management for Long Bone Fracture (OP–21) (82 FR 59428), and
- Median Time to Fibrinolysis (OP–1) (83 FR 37179 through 37186).

From the Efficient Use of Medical Imaging group:

- Thorax CT—Use of Contrast Material (OP–11) (83 FR 37179 through 37186), and
- Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT) (OP–14) (83 FR 37179 through 37186).

The aforementioned measure removals from CMS quality programs and public reporting ultimately result in two of the previously used measure groups, Timeliness of Care and Efficient Use of Medical Imaging, being comprised each of only three measures, which would not produce robust or predictable measure group scores.

Therefore, in this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose

[172] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[173] Centers for Medicare & Medicaid Services. (2019) *Hospital Compare.* Retrieved from: *www.medicare.gov/hospitalcompare: https://www.medicare.gov/hospitalcompare/search.html?*

[174] Centers for Medicare and Medicaid Services (2019, October). Design for Nursing Home Compare. Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/usersguide.pdf.*

[175] Centers for Medicare and Medicaid Services (2019, October 1). Medicare 2020 Part C & D Star Ratings Technical Notes. Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/Prescription DrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf.*

[176] Centers for Medicare and Medicaid Services (2016, June). Technical Notes on the Updated Dialysis Facility. Retrieved from dialysisdata.org: *https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRating Methodology.pdf.*

[177] Ibid.

[178] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41147 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[179] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[180] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[181] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[182] Ibid.

combining three previously used measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one group entitled Timely and Effective Care. We also propose to codify this new group at § 412.190. This new consolidated group would reflect the principles of measure reduction under the Meaningful Measures Initiative and align with the current display of measures on *Hospital Compare.*[183] This consolidation would be necessary to ensure that a sufficient number of measures exist in this group.[184] [185] [186] In general, the TEP supported regrouping of measures into five measure groups with one process measure group (Timely and Effective Care) given the available measures and scheduled removal of measures in the upcoming years.[187]

In order to simulate the potential effects of these proposals, we used October 2019 publicly reported measure data on *Hospital Compare* to test the January 2020 Overall Star Rating to determine how many hospitals would be eligible to receive a star under the proposed measure grouping. Of the 4,576 hospitals that provide acute inpatient care, including CAHs, and reported measures on *Hospital Compare* in October 2019, 180 more hospitals (3,780 hospitals total) would have met the current reporting thresholds (that is, at least three measures in at least three measure groups, one of which must be an outcome group) to receive a star rating with the proposed five measure groups as compared to the original seven measure groups (3,600 hospitals). Additionally, the proposed new grouping would allow approximately 157 additional CAHs, beyond the 1,149 CAHs already receiving a star rating with the current methodology, to receive a star rating. To note, with the current methodology of seven measure groups, these 157 CAHs usually do not meet the minimum threshold to receive a star rating due to serving too few patients to report the underlying measures in each of the individual process groups. The minimum reporting threshold requirements are discussed in section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating of this proposed rule.

The above estimations of how many hospitals would receive a star rating are based on the measure regrouping methodology proposed in this rule; we note that other proposals may also influence hospitals meeting or not meeting reporting thresholds for star ratings. This measure regrouping proposal aligns with the guiding principles of the Overall Star Rating,[188] which include being inclusive of hospitals and measure information, accommodating changes in the underlying measures, and accounting for the heterogeneity of available measures. We invite public comment on our proposed measure groupings and codification of those groupings.

4. Step 3: Calculation of Measure Group Scores

In the past, we have used latent variable modeling (LVM) to calculate measure group scores. In this proposed rule, we propose to replace LVM with a simple average of measure group scores to increase the simplicity of the methodology and predictability of measure weights within the methodology. LVM and the proposal to utilize a simple average of measure group scores is discussed in detail below.

a. Current Approach To Calculating Measure Group Scores Using Latent Variable Modeling

Latent Variable Modeling[189] (LVM) is a statistical approach used to combine or summarize multiple pieces of information, such as hospital quality measures, into a single number, such as measure group scores. LVM is described further within section E.4.a.(1) Latent Variable Modeling Overview below. Notably, LVM estimates loadings, or the contribution of each measure within each of the measure groups, using the data from hospitals that provide acute inpatient and outpatient care, as described in section E.4.a.(2) Latent Variable Modeling Measure Loadings. LVM also produces point estimates and standard errors for each hospitals' measure group score, allowing for the calculation of confidence intervals to assign hospitals with at least three measures in a measure group to ''above,'' ''same as,'' or ''below the national average,'' as described in section E.4.a.(3) Measure Group Performance Categories.

(1) Latent Variable Modeling Overview

Latent Variable Modeling[190] (LVM) is a statistical approach used to combine or summarize multiple pieces of information and has been used to summarize information in a variety of settings ranging from education to healthcare.[191] [192] [193] The purpose for using LVM is to quantify the underlying quality trait, or an aspect of quality, as a number which best explains the correlation and variation of measures in a given group.

In the past, we have employed LVM to estimate measure group scores for each of the seven measure groups. In this context, LVM accounted for the relationship, or correlation, between measures for a given hospital so that measures that are more consistent with each other have a greater influence on the underlying aspect of quality calculated as a measure group score.[194] In addition, the LVM also accounted for differences in the size of each hospital's measure denominator so that measures with larger denominators also have more influence on the measure group score.[195]

When we developed the initial methodology for Overall Star Rating, we investigated multiple approaches to calculating measure group scores, including simple or weighted averages of measures, as well as more complex approaches such as LVM and factor

[183] Centers for Medicare & Medicaid Services. *Hospital Compare.* (2019). Retrieved from *www.medicare.gov/hospitalcompare: https://www.medicare.gov/hospitalcompare/search.html?*

[184] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[185] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[186] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[187] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[188] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[189] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[190] Ibid.

[191] Henderson CR. Best Linear Unbiased Estimation and Prediction under a Selection Model. Biometrics 1975;31:423–47.

[192] Shwartz M, Ren J, Pekoz EA, Wang X, Cohen AB, Restuccia JD. Estimating a composite measure of hospital quality from the Hospital Compare database: differences when using a Bayesian hierarchical latent variable model versus denominator-based weights. Med Care 2008;46:778–85.

[193] Landrum M, Bronskill S, Normand S-L. Analytic Methods for Constructing Cross-Sectional Profiles of Health Care Providers. Health Services and Outcomes Research Methodology 2000;1:23–47.

[194] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[195] Ibid.

analyses.[196] Both the simple and weighted average approaches take the sum of measures, either with equal (that is, simple) or varying weights (that is, weighted), and divide by the number of measures a hospital reports in the measure group. Both LVM[197] and factor analysis[198] attempt to identify underlying traits, in this case quality of acute inpatient and outpatient care, within large datasets, such as hospital measure scores. Each approach was reviewed by the TEP and presented for public input prior to the launch of Overall Star Rating in 2016. We ultimately chose LVM to calculate measure group scores based on support from the TEP,[199] which favored the ability of LVM to utilize data to account for the relationship between measures, measures which are not reported, and sampling variation.[200]

Each LVM assumes that each measure in a measure group reflects information about an underlying aspect or domain of hospital quality as represented by each of the measure groups. For example, safety, mortality, or readmission are each aspects of quality represented by a distinct set of individual measures. Previously, we constructed a separate LVM for each of the seven measure groups. Each LVM estimated a quantitative value, or measure group score, for the group's underlying aspect of quality for each hospital that reports enough measures in each group.

LVM accounts for the correlation between measures by allowing measures that are more consistent with each other to have a greater influence on the measure group scores.[201] The LVM also accounts for differences in the size of each hospital's measure denominator so that measures with larger denominators have more influence on the measure group score, since their measure scores are considered more precise.[202] A measure's influence on the measure group score, or loading, is derived by the LVM, ultimately by using the national performance of each measure, as well as the correlation between measures to find the best combination of measure emphasis for each measure group.[203] Measure loadings are further discussed below in section E.4.a.(2) Latent Variable Model Measure Loadings. The loading represents the measure's relationship to the underlying aspect of quality and therefore, the measure's contribution to the measure group score.[204] Measure loadings were re-estimated for each publication of the Overall Star Rating and were the same value for all hospitals that provide acute inpatient and outpatient care. In other words, LVM accounts for measures which are not reported by estimating and assigning the same measure loading values to all hospitals, regardless of differences in the number of measures hospitals report.

The LVM for each measure group can be explained using the below path diagram presented in Figure 1. In the sample path diagram, the ovals represent the measure group scores, calculated using LVM, and hospital summary scores, calculated by a weighted average of measure group scores. The measure group score is not directly observed but estimated from the LVM using the individual measures. The arrows between the measure group scores and each individual measure represent the relationship of that measure to the aspect of quality reflected by each measure with respect to the other measures in that group; each arrow has a different degree of association, also known as a ''loading'' or coefficient, which is explained in detail within section E.4.a.(2) Latent Variable Modeling Measure Loadings. The small circles on the left represent the residual error within each hospital for each of the measures included in the Overall Star Rating. The residual error (ε) is the variation which could not be explained by the measure group score (random effect).

[196] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[197] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[198] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[199] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[200] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

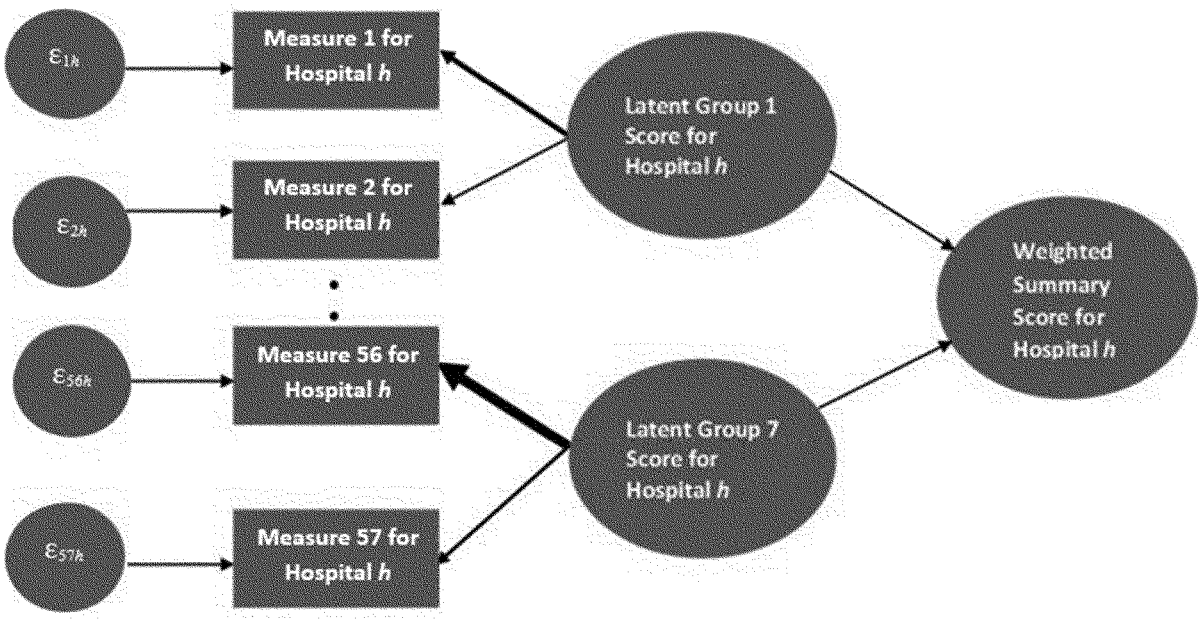
[201] Ibid.

[202] Ibid.

[203] Ibid

[204] Ibid.

Figure 1. Sample Path Diagram of Group-Specific LVM



The LVM equation used to derive a hospital's measure group score is as follows:

$$Y_{khd} = \mu_{kd} + Y_{kd}\alpha_{hd} + \varepsilon_{khd},\ k=1,\ldots,N_d$$

$$\alpha_{hd} \sim N(0,1) \text{ and } \varepsilon_{khd} \sim N(0,\sigma^2_{kd})$$

Let Y_{khd} denote the standardized score for hospital h and measure k in measure group d. α_{hd} is the hospital-specific group-level latent trait (random effect) for hospital h and measure group d and follows a normal distribution [205] with mean 0 and variance 1. The estimated value of α_{hd} will be used as a measure group score. γ_{kd} is the loading (regression coefficient of the latent variable) for measure k, which shows the relationship with the measure group score of measure group d. N_d is the total number of measures in measure group d. The assumption of unit variance here is an innocuous choice of units required to identify the parameter μ_{kd} and γ_{kd}. For detailed descriptions of the LVM model parameters and equation, please see the Overall Hospital Quality Star Rating on *Hospital Compare* Methodology Report (v3.0).[206]

(2) Latent Variable Modeling Measure Loadings

In the past, the LVMs within the Overall Star Rating methodology estimate loadings for each measure within each of the measure groups. A measure's loading indicates its relative contribution to a hospital's measure group score, with higher loadings indicating measures with more influence.[207] A measure's loading is specific to the measure and the same for all hospitals reporting that measure.

A measure loading is a regression coefficient,[208] which is estimated through the LVM by using a statistical approach called maximum likelihood. Maximum likelihood [209] uses the observed data for each measure in a group, including the national performance on the measure and the measure's relationship to other measures in the group, to find the best combination of measure emphasis for the aspect of quality represented by the measure group. In other words, measure score variation nationally and the correlation between measures in a measure group influence measure loadings. Measures with more variation nationally and higher correlations with other measures in a measure group have higher measure loadings because such measures are assumed to convey more information about a given aspect of acute inpatient and outpatient quality of care than measures with limited variation or less correlation with other measures in the same group.

The LVM also accounts for sampling variation, or differences in the amount of information available for different hospitals to estimate loadings. For example, for each measure, some hospitals may report a score based on data from fewer cases while other hospitals report scores based on more cases, resulting in differing precision for each hospital's individual measure score. We accounted for these differences in case size by giving more weight to measures with larger denominators. Measure scores based on larger denominators are assumed to have more precise measure scores and therefore contribute more when estimating measure loadings. The weighted likelihood equation for accounting for sampling variation within each measure group is as follows:

[205] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[206] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[207] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[208] Ibid.

[209] Cole, S.R., Chu, H., & Greenland, S. (2014, January 15) ''Maximum likelihood, profile likelihood, and penalized likelihood: a primer.'' American journal of epidemiology 179.2: 252–260.

$$L = \prod_{k=1}^{K} \prod_{h=1}^{H} (L(Y_{khd}))^{w_{khd}} \qquad w_{khd} = \frac{n_{khd}}{\sum_{h=1}^{N_{kd}} n_{khd}} \times N_{kd}$$

L is the likelihood function. N_{kd} is the total number of hospitals for measure k in measure group d and n_{khd} is the denominator for hospital h and measure k in measure group d. A hospital with a larger denominator will be weighted more in the LVM. The specified weighted likelihood is maximized with respect to all the parameters in the first LVM equation.

Measures with higher loadings have a greater association and impact on the measure group score than measures with lower loadings. Measures highly correlated with other measures in the measure group and the measure group score, measures with large denominators, and measures more commonly reported are likely to have higher loadings because they are generally expected to provide more information about a hospital's quality profile than other measures.

In February 2019, we made an update to remove measures with statistically significant negative loadings from the LVM calculations.[210] Measure loadings can be positive or negative. Measures with statistically significant negative loadings have an inverse relationship with other measures in the group. Although negative loadings rarely occur and are almost always statistically insignificant, some stakeholders, including those on the TEP, and during a public input period, expressed concern that measures with negative loadings could be perceived to promote lower quality with respect to measure group scores.[211] [212] [213] [214] [215] While internal analyses have not identified any substantial effect of measures with negative loadings on hospital star ratings, CMS understood the theoretical concern and decided to remove measures with statistically significant negative loadings, beginning in February 2019.[216]

Measure loadings were re-estimated for each publication of the Overall Star Rating and could change dynamically as the measure methodologies, hospitals' performance, and the relationship between measures evolved.

(3) Measure Group Performance Categories

We reported Overall Star Rating measure group performance categories to individual hospitals that provide acute inpatient and outpatient care and on *Hospital Compare* in order to provide context for measure group scores in comparison to all other hospitals in the nation. Performance categories were not calculated by the LVM, nor did they have influence on star ratings. Rather, they were assigned categories of ''above'', ''same as'', or ''below the national average'' as additional public information on each of the measure groups a hospital reports by comparing a hospital's measure group score to the national average measure group score.

These measure group performance categories were assigned using information from the LVM, separate from measure loadings. For each measure group, LVM produced a point estimate[217] and standard error[218] for each hospital's measure group score that we used to construct a 95 percent confidence interval.[219] A point estimate is a statistic close to the exact value in a dataset, whereas the standard error is a measure of the variability, or how spread out individual points are around the average in the dataset, and both are used to construct a confidence interval, or a range of reasonable values in which we expect a value to fall.[220] We compared this 95 percent confidence interval to the national mean measure group score. Measure group scores with confidence intervals that fall entirely above the national average were considered ''above the national average'', confidence intervals that include the national average were considered ''same as the national average'', and confidence intervals that fall entirely below the national average were considered ''below the national average''.

b. Proposal To Use a Simple Average of Measure Scores To Calculate Measure Group Scores

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to eliminate use of the LVM and instead use a simple average of measure scores to calculate measure group scores beginning with the Overall Star Rating in CY 2021 and subsequent years.

We recognize that LVM may be challenging for stakeholders to understand and explain to others. Stakeholders, specifically providers, serving on the Provider Leadership Work Group and during a public input period,[221] have requested a less complex methodology that can be easily understood by their organization, explained to their patients, and used to identify areas for quality improvement. In addition, LVM is a data-driven statistical approach that relies on underlying measure data to re-estimate measure loadings[222] for each release of the Overall Star Rating. Since the underlying measure data is refreshed variably based on the measure and CMS quality program requirements—either quarterly, biannually, or annually—the estimated measure loadings based on the underlying data for each annual publication of the Overall Star Ratings were unpredictable, further complicating understanding of the methodology and efforts to allocate resources for quality improvement.

Therefore, in this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to discontinue the use of the LVM, and instead, propose to adopt a simple

[210] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[211] Centers for Medicare & Medicaid Services. (2015, June 8). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[212] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[213] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[214] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[215] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[216] Centers for Medicare & Medicaid Services. (2018, November 30). *Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report.* Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[217] Illowsky, B., & Dean, S. (2013). Introductory Statistics. Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[218] Ibid.

[219] Ibid.

[220] Ibid.

[221] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[222] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

average of measure scores to calculate measure group scores. This method would average the measure scores a hospital reports within a given measure group, which have been standardized, to calculate the measure group scores. In other words, we would take 100 percent divided by the number of measures reported to give us the percentage each measure would weigh; this measure weight would then be multiplied by the standardized measure score to calculate the measure's weighted score. Then, all of the individual measure weighted scores within a group would be added together to calculate the measure group score. We also propose to codify this policy at § 412.190.

For example, if a hospital reports all eight measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by eight measures reported (100 percent / 8 reported measures = 12.5 percent) and each measure would be weighted 12.5 percent within the group. The standardized measure scores for each of the eight measures would then be multiplied by the weight of 12.5 percent and summed to determine the Safety of Care measure group score. See Table 47 for an example of measure weights in which a hospital reports all eight measures within Safety of Care. For the Readmission measure group for example, a hospital's score on the Hospital-Wide, All-Cause Unplanned Readmission measure, which includes most patient admissions at a hospital, would have the same influence as their score on the condition specific Chronic Obstructive Pulmonary Disease (COPD) Readmission measures, which includes significantly fewer patients.

Example of Simple Average of Measure Scores To Calculate Measure Group Scores

$$\text{Measure group score} = [(-1.13*0.125) + (-0.75*0.125) + (0.09*0.125) + (1.21*0.125) + (0.97*0.125) + (0.98*0.125) + (0.46*0.125) + (0.02*0.125)] = 0.23$$

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TABLE 47: EXAMPLE OF SIMPLE AVERAGE OF MEASURE SCORES TO CALCULATE OF SAFETY OF CARE MEASURE GROUP SCORE

Measure Name	Example Measure Score	Standardized Measure Score	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	12.5%	-0.14	0.23
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	-0.75	12.5%	-0.09	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.09	12.5%	0.01	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	1.21	12.5%	0.15	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.97	12.5%	0.12	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.98	12.5%	0.12	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	12.5%	0.06	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	12.5%	0.003	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

Under certain circumstances, hospitals may not report all measures within a measure group. However, we note that the proposed minimum threshold is three measures within three measure groups, one of which must be Mortality or Safety of Care. Once this threshold is met, any additional measures or groups may contribute to a hospital's star rating. We refer readers to section E.6. Step 5 Application of Minimum Thresholds for Receiving a Star Rating where the proposed minimum threshold is discussed. As an example, if a hospital reports three measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by three measures reported (100 percent 3 reported measures = 33.3 percent) and each measure would be weighted 33.3 percent within the group. The standardized measure scores for each of the three measures would then be multiplied by the weight of 33.3 percent and summed to determine the Safety of Care measure group score. See Table 48 for an example of measure weights in which a hospital reports three measures within Safety of Care.

Example of Simple Average of Measures Scores To Calculate Measure Group Scores When Measures Are Not Reported

Measure group score = $[(-1.13*0.333) + (0.46*0.333) + (0.02*0.333)] = -0.22$

TABLE 48: EXAMPLE OF SIMPLE AVERAGE OF MEASURE SCORES TO CALCULATE SAFETY OF CARE MEASURE GROUP SCORE WHEN MEASURES ARE NOT REPORTED

Measure Name	Example Measure Score	Standardized Measure Score*	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score*
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	33.3 %	-0.38	-0.22
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	NA	NA	NA	NA	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	NA	NA	NA	NA	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	NA	NA	NA	NA	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	NA	NA	NA	NA	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	NA	NA	NA	NA	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	33.3 %	0.15	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	33.3 %	0.006	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

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As previously noted, LVM accounted for measures which are not reported by uniformly assigning the same loading for a measure to hospitals that provide acute inpatient and outpatient care,[223] whereas use of a simple average of measure scores would result in hospitals having varying measure weights depending on differences in the number of measures reported. For example, if a hospital reports three of the eight measures in the Safety of Care measure group, each measure would be weighted at 33 percent within that group. On the other hand, a hospital that reports all eight measures in the Safety of Care measure group would have a different weighting of 12.5 percent for each measure within the measure group. We simulated the possible range of measure weights using the data used for January 2020 Overall Star Rating (October 2019 public reporting data), which included 51 measures. We simulated the results using the measure group weights proposed in section E.5.a.(2) Proposal to Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores; outcome and patient experience measure groups were weighted 22 percent and the process group was weighted 12 percent. Taking into account the measure group weights applied later in the methodology, the minimum effective measure weight, or the percentage of the hospital summary score based on a single measure, would be 3 percent for a hospital reporting all 51 measures and the maximum effective measure weight would be 33 percent for another hospital reporting the minimum

[223] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

threshold number of nine measures (at least three measures in at least three groups). Hospitals with more measures will have lower measure weights for each measure, whereas hospitals with fewer measures will have higher measure weights for each measure. The number of measures included in the Overall Star Rating varies for each publication depending on measure removals from and additions for public reporting.

Using a simple average of measure scores to calculate measure group scores would be responsive to stakeholder feedback that requested CMS increase the simplicity of the methods and the predictability of measure emphasis between publications.[224] [225] [226] [227] Using a simple average of measure scores would increase the predictability of measure emphasis by allowing hospitals to anticipate equal measure weights across the measures they report within a given group. While there may be differences in measure emphasis between hospitals that provide acute inpatient and outpatient care based on differences in measure reporting, a simple average of measure scores will be responsive to stakeholder feedback and make the methodology easier for stakeholders to understand, interpret, and explain to patients.

Since measure loadings are an artifact of the LVM approach, they would no longer be calculated under the proposed new method using a simple average of measure scores. In addition, since the point estimates and standard errors used to calculate 95 percent confidence intervals and assign hospital measure group performance to ''above,'' ''same as,'' or ''below the national average'' were products of the LVM approach, measure group performance categories will no longer be available under the proposed new method using a simple average of measure scores. However, we intend to continue to publicly display alternative summaries of hospital performance within measure groups for transparency and patient usability. Should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, measure group performance categories would still be available in the same manner described above.

In crafting this proposal, we also considered continuing to utilize LVM as we have in the past and as discussed in the section above. Ultimately, we chose to propose to discontinue the use LVM because of the complexity associated with understanding how measure loadings are empirically assigned with the LVM and contribute to the measure group scores. We invite public comment on our proposals to use a simple average of measure scores to calculate measure group scores and to codify this policy at § 412.190 as discussed.

c. Proposal to Standardize Measure Group Scores

Standardizing[228] scores is a way to make varying scores directly comparable by putting them on a common scale. While standardization is used in other parts of the methodology, particularly to standardize measure scores within the first step of methodology, it was previously not necessary to standardize measure group scores when using statistical modeling, such as LVM. In the absence of statistical modeling, under the use of the proposed simple average of measure scores as discussed in section E.4.b. Proposal to Use a Simple Average of Measure Scores to Calculate Measure Group Scores, the distributions and interpretations of measure group scores may differ. For example, a 0.5 measure group score in Safety of Care may not conceptually be similar to a 0.5 measure group score in Patient Experience, exaggerating the influence of some measure groups when calculating a weighted average of measure group scores.

Therefore, for the Overall Star Rating beginning with CY 2021 and subsequent years, we propose to standardize measure group scores. More specifically, we propose to standardize measure group scores by calculating Z-scores for each measure group. As mentioned in section E.2.d. Measure Score Standardization, a Z-score[229] is a standard deviation[230] score which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. Z-scores would be calculated by subtracting the national average measure group scores from each hospital's measure group score and dividing by the standard deviation across hospitals. Standardization of measure group scores would occur prior to combining measure group scores through a weighted average to calculate summary scores, and would result in all measure group scores centered near zero with a standard deviation[231] of one. We also propose to codify this policy at § 412.190.

See Table 49 for an example of how measures would be combined through a simple average of measure scores to calculate measure group scores and then how the measure group scores would be standardized. The standardization of measure group scores would not impact hospital performance within the measure group or the natural distribution of scores. As a result of standardization,[232] mean group scores and standard deviations would become more similar across measure groups. We simulated the potential effects of standardization using data from the January 2020 publication of Overall Star Rating and found that hospital summary scores with and without standardization of measure group scores are highly correlated with a Pearson correlation of 0.975, indicating that standardizing measure group scores does not substantially alter hospital performance assessment. We note that, should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, we would not need to standardize measure group scores.

We invite public comment on our proposal to standardize measure group scores and codify this policy at § 412.190.

d. Proposal To Stratify Readmission Measure Group Scores

(1) Current Measure Group Scores Without Stratification

In the past, we have not stratified or adjusted any of the measures, measure groups, summary scores, or star ratings by social risk factor variables within the Overall Star Rating methodology, primarily based on the original guiding principles of the Overall Star Rating.

[224] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[225] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[226] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[227] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[228] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[229] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[230] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[231] Ibid.

[232] Ibid.

The Overall Star Rating is meant to summarize the existing quality measure information that is publicly reported through CMS programs, including Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, on *Hospital Compare* or its successor websites. Individual measures undergo rigorous development and reevaluation processes under each program that include extensive analytic testing and stakeholder engagement. As such, individual measure methodologies as specified under each program, including approaches to risk adjustment, are included within the Overall Star Rating. As measure data and methodologies are updated under each of the programs, they are subsequently reflected within the Overall Star Rating methodology. CMS' Overall Star Rating development contractor has engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the Overall Star Rating. Throughout that engagement, some stakeholders, primarily providers, requested incorporation of social risk factor adjustment within the Overall Star Rating, while other stakeholders expressed concerns regarding adjustment in general or the specific variables available for adjustment.[233] Specifically, some stakeholders have requested social risk factor adjustment of the readmission measures or the Readmission measure group.[234] [235] Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for social risk for public reporting.[236]

We seek comment on our proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, and an alternative not to stratify the Readmission measure group based on the proportion of dual-eligible patients.

(2) Proposal To Stratify Only the Readmission Measure Group Scores

In this proposed rule, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to stratify only the Readmission measure group score by hospitals' proportion of dual-eligible patients and codify this at § 412.190. We propose to specifically stratify only the Readmission measure group, and not other measure groups, based on hospitals' proportion of dual-eligible hospital discharges, to be responsive to select stakeholder concerns that some hospitals providing acute inpatient and outpatient care face unique challenges preventing readmissions among patients with complex social risk factors,[237] and to align with the payment adjustment recently implemented for HRRP payment determination (82 FR 38231 through 38237). We propose to utilize and repurpose the same peer group quintiles assigned by the HRRP annually. We propose to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. We also propose that in the event a hospital's proportion of dual-eligible patient data is missing, CMS would not adjust that hospital's Readmission measure group score and that hospital would retain its original, unadjusted Readmission measure group score, as calculated through a simple average of their measure scores.

The proposed stratification of the Overall Star Rating Readmission measure group score would use the same dual-eligible variable and a similar peer grouping approach as is used in the HRRP for payment determinations (82 FR 38231 through 38237). To be clear, the Overall Star Rating is not used to determine hospital payments. Dual-eligible[238] patients are those that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service (FFS) and Medicare Advantage patient discharges (42 U.S. Code § 1315b(f)). Dual-eligible status is consistently captured for patients and available through enrollment files, which are updated annually, and does not require extrapolation from area of residence variables, such as census or community surveys.

In 2016, the 21st Century Cures Act mandated that CMS determine hospital penalties for readmissions that account for social risk factors through a transitional methodology that calculates excess readmissions ratios within hospital peer groups defined by the percentage of dual-eligible patients served by the hospital within the HRRP (Pub. L. 114–255). Section 15002 of the 21st Century Cures Act, adding a new section 1886(q)(3)(D) and (E) to the Act, also indicated this methodology could be characterized as a ''transitional adjustment'' and that the Secretary of Health and Human Services may revise the stratification methodology, taking into account recommendations made on risk-adjustment methodologies for HRRP based on the studies conducted under the IMPACT Act by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the role of socioeconomic status in Medicare's value-based purchasing program.

In the FY 2018 IPPS/LTCH PPS rule, we finalized our HRRP proposal to implement a methodology that categorizes participating hospitals that provide acute inpatient care into five peer groups by quintiles, based on the proportion of dual-eligible patients to total patients served by the hospital. The methodology uses the median excess readmission ratio of hospitals within each of the five peer groups as the threshold to assess hospital performance on each measure (82 FR 38231 through 38237). The excess readmission ratio measures a hospital's relative performance and is the ratio of predicted-to-expected readmissions.[239] This methodology was implemented within HRRP in FY 2019 as announced in the associated correction notice (82 FR 49837). The individual readmission measures included within HRRP and publicly reported on *Hospital Compare*

[233] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[234] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[235] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[236] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[237] National Quality Forum. (2014, August). Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. Retrieved from: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=77474.*

[238] Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.*

[239] Centers for Medicare & Medicaid Services. (2019, Novemebr 19). *Hospital Readmissions Reduction Program (HRRP).* Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program.*

or its successor website are not adjusted for social risk factors.

The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients is intended to provide consistency between the current stratification method used for the HRRP and the Overall Star Rating methodology. It is not in any way intended to suggest a new policy direction for the more general question of whether CMS programs should employ social risk factor adjustment methods of any kind. The rationale for this proposal is based on alignment between the two CMS efforts. If changes are made in the future to the HRRP stratification approach, CMS may consider similar changes to the Overall Star Rating methodology through future rulemaking. Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for social risk for public reporting.[240] The stratification approach in the HRRP has been recommended for removal based on HHS recommendations in a second Report to Congress, mandated by the IMPACT Act of 2014, titled ''*Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs*'' submitted by ASPE on June 29, 2020.[241] The report recommends not adjusting outcome measures for social risk factors in CMS programs and recommends that, eventually, stratification of hospitals by the proportion dual-eligible patients should be removed from the HRRP. CMS is currently reviewing the report recommendations and considering how to incorporate these recommendations within CMS programs.

The Overall Star Rating uses individual measure scores, as calculated under the quality programs and reported on *Hospital Compare* or its successor website, to calculate measure group scores. Individual measure methodologies, including current and future approaches to risk adjustment for each measure, as specified in the measures, are inherently included within the Overall Star Rating. Since the Overall Star Rating utilizes the individual measure scores as publicly reported, it is not appropriate to apply social risk factor adjustment to the individual measure scores for the purpose of the Overall Star Rating. In addition, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections where the onset of adverse events occur in the hospital setting should not be influenced by a patient's socioeconomic status.[242] [243] The proposed stratification approach would stratify only the Readmission measure group scores based on a comparison to other hospitals with similar proportions of dual-eligible patients, as opposed to in comparison to all hospitals.

Since the Overall Star Rating is not used to determine hospital payment, we propose calculating the readmission measure group score within each dual-eligible peer group. In the formula below, α_h is the readmission group score for hospital *h*, $\bar{a}$ is the national average of readmission group score, $\bar{a}_{peer\ group\ j}$ is the average readmission group score for dual-eligible peer group *j* (*j* = 1, 2, . . . , 5).

$$\tilde{\alpha}_{h|peer\ group\ j} = \alpha_h * \left\{1 + \frac{\bar{\alpha}}{\alpha_h}\left(1 - \frac{\bar{\alpha}_{peer\ group\ j}}{\bar{\alpha}}\right)\right\}$$
$$= \alpha_h + \bar{\alpha} - \bar{\alpha}_{peer\ group\ j}$$

During public input periods,[244] CMS' contractor received feedback from stakeholders, specifically providers, encouraging alignment between Overall Star Rating and CMS programs, with specific mention of alignment with HRRP's approach to peer grouping by dual-eligibility. In response to stakeholder feedback to promote alignment between programs and provide consistent measurement standards for providers, we propose to utilize the same dual-eligible quintiles as HRRP for the Readmission measure group. Applying stratification to the Readmission measure group scores based on proportion of dual-eligible patients would align with HRRP (82 FR 38231 through 38237). Consistent with HRRP, stratifying the Overall Star Rating Readmission measure group would assign hospitals to one of five peer groups based on the proportion of dual-eligible patients. For FY 2019, the range of proportion of dual-eligible patients within each of the hospital peer group quintiles for HRRP are as follows: 0 to 13.69 percent, 13.70 to 18.40 percent, 18.41 to 23.23 percent, 23.24 to 30.98 percent, 30.99 to 100 percent for peer groups one, two, three, four, five, respectively. We propose to utilize and repurpose the same peer group quintiles assigned by the HRRP, annually. Peer groups for the Overall Star Rating would not be exact quintiles, as a greater number of hospitals are included in Overall Star Rating than those participating in HRPP. The Overall Star Rating includes hospitals providing acute inpatient and outpatient care, including both subsection (d) hospitals and CAHs, whereas HRRP only includes subsection (d) hospitals. We refer readers to section A.1.b. Subsection (d) Hospitals and B. Critical Access Hospitals in the Overall Star Rating for more information on the hospitals

[240] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[241] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[242] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[243] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[244] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

included within the Overall Star Rating. For the 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 3,077 hospitals participated in HRRP received a readmission score. Since the hospitals within the Overall Star Rating that do not participate in HRRP would not already be assigned to a peer group by the HRRP methodology, we propose to calculate their proportion of dual-eligible patients and assign them to one of the five peer groups based on the HRRP designated peer groups.

As stated above, we propose to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. This is necessary to maintain alignment with HRRP so that hospitals in HRRP are assigned to the same peer group within both HRRP and the Overall Star Ratings. As also stated above, we propose to not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data. This is necessary because we would not have the dual-eligible data necessary to produce an adjusted score.

(i) Other Methods Considered

In developing our proposal, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating dataset, and not solely based on those participating in HRRP. Using all hospitals to calculate peer group quintiles would be more consistent with other aspects of the methodology that use all hospital data, such as the calculation of measure group scores and weighted average of measure groups scores to calculate summary scores. However, calculating quintiles based on all hospitals would create potential misalignment between quintiles, and therefore peer group assignment, for HRRP and the Overall Star Rating Readmission measure group. More specifically, if dual-eligible quintiles were recalculated based on all hospitals within the Overall Star Rating, some hospitals that are within both HRRP and the Overall Star Rating would be assigned to different peer groups in each of the two methodologies based on the different dual-eligible quintile cutoffs.

Using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*), we simulated calculation of quintiles based on all hospitals, 155 (5.04 percent) of the 3,174 HRRP hospitals would move down a peer group quintile; that is, they would move to a quintile with a lower proportion of patients that are dual-eligible, indicating their patient case mix has lower social risk. Under this simulation, specifically, 23 (3.67 percent) hospitals assigned dual-eligible quintiles in HRRP would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 40 (6.46 percent) hospitals would move from peer group three to peer group two, 48 (7.74 percent) hospitals would move from peer group four to peer group three, and 44 (7.28 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

For the January 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 1,307 hospitals did not participate in HRRP. Similarly, using the same simulated calculation of quintiles based on all hospitals, 90 (6.89 percent) of the 1,307 non-HRRP hospitals would move down a peer group quintile if calculating based on all hospitals than they would have if using only HRRP hospitals. Specifically, 9 (0.69 percent) hospitals would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 31 (2.37 percent) hospitals would move from peer group three to peer group two, 27 (2.07 percent) hospitals would move from peer group four to peer group three, and 23 (1.76 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

After calculation, mean Readmission measure group scores would be the same for each hospital peer group, resulting in more similar measure group scores across hospital peer groups. While stratifying results in more comparable measure group scores across peer groups of proportions of dual-eligible patients, the effect on the Overall Star Rating Readmission measure group is modest; our simulations showed a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

In developing our proposal, as discussed in section a. Alternatives Considered, we also considered not stratifying the Readmission measure group and retaining the current measure group without stratification based on proportion of dual-eligible patients within the calculation of the Overall Star Ratings. CMS' Overall Star Rating development contractor engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the methodology. Throughout that engagement, some stakeholders expressed concerns regarding adjustment for social risk factors in general, adjustment for social risk factors within the Overall Star Rating methodology, or use of specific social risk factor variables that are currently available for adjustment.[245] Most stakeholders agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections, and therefore, not appropriate to be applied at aggregated levels, such as the Overall Star Rating.[246] [247] Some stakeholders, including patients and patient advocates, expressed concern that stratifying the Readmission measure group by the proportion of dual-eligible patients would result in a misrepresentation of quality of care at hospitals, particularly for dual-eligible patients, and would be confusing to patients as consumers of the Overall Star Rating.[248] [249] [250] Furthermore, the effect of stratifying the Overall Star Rating Readmission measure group score is negligible, as shown through a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October

[245] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[246] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[247] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[248] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[249] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[250] National Quality Forum. (2019, November 6). *National Quality Forum Hospital Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

2019 publicly reported measure data on *Hospital Compare*).

CMS is also considering recommendations on risk-adjustment recently submitted to Congress. On behalf of the Secretary for Health and Human Services (HHS), ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations on risk-adjustment for CMS programs and quality efforts, including the Overall Star Rating. For publicly reported quality measures, recommendations are that ''*Quality measures, resource use measures, and composite scores should not be adjusted for social risk factors for public reporting.*'' Instead, recommendations are for quality and resource use measures to be reported separately for dual-eligible beneficiaries and other beneficiaries in order to monitor disparities and improvements over time. The report indicates for public reporting, it is also important to hold providers accountable for outcomes, regardless of social risk. Overall, the report lays out a comprehensive approach for CMS programs to move towards incentivizing providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. The report indicates proposed solutions that address only the measures or programs, without considering the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes.

However, we are ultimately proposing to stratify the Readmission measure group based on the proportion of dual-eligible patients to align with HRRP and be responsive to stakeholder feedback, particularly form health care providers. However, considering inconsistent feedback received from stakeholders and HHS recommendations for CMS programs, we also seek comment on an alternative to retain the Readmission measure group calculation without stratification based on the proportion of dual-eligible patients.

We invite public comment on our proposals to: (1) Stratify only the Readmission measure group score based on the proportion of dual-eligible patients by using peer groups annually designated by the HRRP, (2) assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP, (3) not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data, and (4) codify this policy at § 412.190. We refer readers to section a. Alternatives Considered where we seek comment on the alternative to not stratify the Readmission measure group score based on the proportion of dual-eligible patients.

5. Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores

a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

(1) Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the past, we have calculated hospital summary scores as a weighted average of measure group scores. That is, each measure group score is multiplied by the assigned weight for that group, and then the weighted measure group scores are summed to calculate the hospital summary score. The measure group weights were determined based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program [251] in that outcome measures are given more weight than process measures. Specifically, the Mortality, Safety of Care, Readmission, and Patient Experience measure groups are each weighted 22 percent and the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups are each weighted 4 percent. In 2015, CMS' contracted development team engaged stakeholders for input on the measure group weights through the TEP,[252] the Patient & Advocate Work Group, and a public input period.[253] In general, stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The development contractor included this topic in several past public input periods,[254] [255] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme.

(2) Proposal To Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue to calculate hospital summary scores through a weighted average of measure group scores with a similar weighting scheme that continues to assign more weight to the outcome and patient experience measure groups and less weight to the process measure group. Specifically, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to weight each of the outcome and patient experience measure groups—Mortality, Safety of Care, Readmission, and Patient Experience—at 22 percent, and the proposed combined process measure group, Timely and Effective Care (we refer readers to section E.3.b. Proposed New Measure Group and Continuation of Certain Groups of this proposed rule), at 12 percent. We also propose that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. We refer readers to an example equation and Table 49. We also propose to codify the measure group weightings at § 412.190 and summary score calculations at § 412.190.

Example of Weighted Average of Measure Group Scores to Calculate Summary Scores

$$\text{Summary score} = [(-0.70*0.22) + (0.23*0.22) + (-0.76*0.22) + (-1.13*0.22) + (-0.25*0.12)] = -0.55$$

[251] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 FR 49567 (Aug 17, 2015) (to be codified at 42 CFR parts 412).

[252] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[253] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[254] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[255] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

TABLE 49: EXAMPLE OF SUMMARY SCORE CALCULATION AND STAR RATING ASSIGNMENT

Measure Groups	Example Group Scores*	Standardized Example Group Scores*	Measure Group Weights	Weighted Standardized Example Group Scores*	Summary Score Calculation*
Mortality	-0.45	-0.70	22 %	-0.15	-0.55
Safety of Care	0.16	0.23	22 %	0.05	
Readmission	-0.35	-0.76	22 %	-0.17	
Patient Experience	-0.93	-1.13	22 %	-0.25	
Timely and Effective Care	-0.07	-0.25	12 %	-0.03	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

In developing our proposal, we also considered equal measure weights across all the measure groups, such that each measure group would be weighted 20 percent. We ultimately chose to propose to weight outcome measures more, because this was vetted and supported by stakeholders and is consistent with past and current stakeholder feedback that outcome measures capture important aspects of quality and are more important to patients.[256] [257]

We invite public comment on our proposals to: (1) Continue to calculate hospital summary scores by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores; (2) continue to weight outcome and patient experience measure groups, (that is, Mortality, Safety of Care, Readmission, and Patient Experience groups) at 22 percent; (3) weight the proposed Timely and Effective Care process measure group at 12 percent; and (4) codify these policies at § 412.190.

b. Reweighting Measure Group Scores To Calculate Summary Scores

(1) Current Reweighting Measure Group Scores To Calculate Summary Scores

In the past, if a hospital did not report or have sufficient measures for a given measure group under the Overall Star Rating methodology, the weights of those measure groups would be redistributed proportionally across the measure groups for which the hospital did report sufficient measures. Generally, the four outcome measure groups were weighted at 22 percent each, and the three process measure groups were weighted at 4 percent each. The approach to proportioning weights when a hospital did not report enough measures for one or more measure groups was similar to the Hospital VBP Program where the weighting of groups is redistributed where one or more groups are not reported,[258] and was vetted by stakeholders for the Overall Star Rating through TEP [259] engagement and a public input period.[260]

(2) Proposal to Reweight Measure Group Scores To Calculate Summary Scores

Moving forward, we propose to continue to reweight measure group scores. Taking into consideration the proposed new measure grouping (we refer readers to section 5 E.3.b. Proposed New Measure Group and Continuation of Certain Groups) and the proposed Timely and Effective Care process measure group weighting of 12 percent (we refer readers to section E.5.a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores), for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to re-distribute measure group weights for measure groups which a hospital does not have sufficient measures within the Overall Star Rating methodology. Once a hospital meets the reporting threshold to receive a star rating, which is having at least three measure groups each with at least three measures, any additional measures and measure groups contribute to their star rating (we refer readers to section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating). In other words, once the reporting thresholds are met, a hospital would need to report at least one measure in each group and the weight of any measure group that does not have at least one measure will be re-distributed amongst the other measure groups. Specifically, we propose to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups, to ensure the relative weight between groups is preserved. We would calculate this by subtracting the standard weight percentage of the group that does not meet the minimum threshold from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. If a hospital does not meet the threshold for two groups, then those two groups' standard weight percentages are added together before subtracting from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. We also propose to codify this at § 412.190. These calculations are illustrated in the three examples below.

For example, if a hospital does not report at least one measure within the Timely and Effective Care measure group, the group's 12 percent weight would be subtracted from the total of

[256] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[257] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[258] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 77 FR 53606 (August 31, 2012) (to be codified at 42 CFR parts 412, 413, 424 and 476).

[259] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[260] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

100 (100 − 12 = 88) and then each of the measure group weights for that hospital would be determined using the new total of 88 (Mortality weight: 22/88 = 25 percent, Safety of Care weight: 22/88 = 25 percent, Readmission weight: 22/88 = 25 percent, and Patient Experience weight: 22/88 = 25 percent). This example is illustrated in Table 50.

TABLE 50: EXAMPLE OF REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT TIMELY AND EFFECTIVE CARE MEASURE GROUP

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	25%
Safety of Care	22%	25%
Readmission	22%	25%
Patient Experience	22%	25%
Timely and Effective Care	12%	--

As another example, if a hospital does not report at least one measure within the Readmission measure group, the group's 22 percent weight would be subtracted from the total of 100 (100 − 22 = 78) and then each of the measure group weights for that hospital would be determined using the new total of 78 (Mortality weight: 22/78 = 28.2 percent, Safety of Care weight: 22/78 = 28.2 percent, Patient Experience weight: 22/78 = 28.2 percent, and Timely and Effective Care weight: 12/78 = 15.4 percent). This example is illustrated in Table 51.

TABLE 51: EXAMPLE REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT READMISSION MEASURE GROUP

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	28.2%
Safety of Care	22%	28.2%
Readmission	22%	--
Patient Experience	22%	28.2%
Timely and Effective Care	12%	15.4%

This same principle would apply if a hospital did not have at least one measure reported in two measure groups. We propose that a hospital must report at least three measure groups, each with at least three measures, one of which must be Mortality of Safety of Care, in order to receive a star rating; once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the Overall Star Rating calculation, including measures groups with as few as one measure (we refer readers to section E.6.b. Proposals to Update the Minimum Reporting Thresholds for Receiving a Star Rating). If a hospital does not report at least one measure within both the Safety of Care and Timely and Effective Care measure groups, the groups' 22 and 12 percent weights would be subtracted from the total of 100 (100 − 22 − 12 = 66) and then each of the measure group weights would be determined using the new total of 66 (Mortality weight: 22/66 = 33.3 percent, Readmission weight: 22/66 = 33.3, and Patient Experience weight: 22/66 = 33.3 percent). This example is illustrated in Table 52.

TABLE 52: EXAMPLE REWEIGHTING FOR A HOSPITAL WHICH DOES NOT REPORT SAFETY OF CARE AND TIMELY AND EFFECTIVE CARE MEASURE GROUPS

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	33.3%
Safety of Care	22%	--
Readmission	22%	33.3%
Patient Experience	22%	33.3%
Timely and Effective Care	12%	--

We invite public comment on our proposals to reweight measure group scores and codify at § 412.190.

6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating

a. Current Minimum Measure and Group Thresholds for Receiving a Star Rating

In the past, in order to receive a star rating, hospitals that provide acute inpatient and outpatient care had to publicly report sufficient measures to receive a star rating. Specifically, a minimum threshold was set to require at least three measure groups (one being an outcome group—that is, Mortality, Safety of Care, or Readmission), with at least three measures in each of the three groups. Additionally, in the past, once a hospital met the minimum measure and measure group thresholds, any additional measures and groups, including groups with as few as one measure, the hospital reported were included in the calculation of their star rating. These reporting thresholds were applied based on the guiding principle of information inclusivity, in that it allowed as many hospitals as possible to receive a star rating while also maintaining face validity and reliability of the Overall Star Rating methodology, and were vetted through TEP and public comment stakeholder engagement.[261] [262]

In 2017, the CMS' Overall Star Rating development contractor vetted the minimum reporting thresholds through the TEP and public input.[263] In December 2017,[264] we updated the order of steps in the methodology for which minimum thresholds are applied; instead of applying minimum thresholds in step 6, after the assignment of hospitals to star ratings, we applied them in step 5, prior to the assignment of hospitals to star ratings so only hospitals meeting the threshold were included in the relative k-means clustering algorithm.[265] K-means clustering [266] is the algorithm used to assign hospital summary scores to one of five star ratings. An overview of k-means clustering is provided in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating below.

b. Proposals To Update the Minimum Reporting Thresholds for Receiving a Star Rating

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue a similar threshold as previously used, but with modification. We propose that hospitals must report at least three measures for three measures groups, however, one of the groups must specifically be the Mortality or Safety of Care outcome groups. We believe this would increase the comparability of hospitals through the requirement of specific measure groups to receive a star rating. We also believe that this would ensure that, in order to receive a star rating, hospitals have information available on important indicators of acute inpatient and outpatient quality of care—mortality and safety of care—that reflect survival and preventable complications or infections following care and are, therefore, important to patients in making healthcare decisions, as indicated by the Patient & Patient Advocate Work Group. We are also proposing to codify this minimum measure group threshold at § 412.190.

However, we are aware that a requirement for at least three measures within the Mortality or Safety of Care groups would simultaneously limit the number of hospitals eligible to receive a star rating, particularly reducing the number of small, low volume hospitals with too few cases to report the individual measures. Furthermore, certain entities, such as CAHs, are not required to report safety measures (for example, healthcare-associated infections and PSI–90) as part of HAC Reduction Program (78 FR 50725 to 50728).[267] In January 2020, 125 hospitals did not report at least three measures in either the Mortality or Safety of Care groups. Of those 125 hospitals without at least three measures in either the Mortality or Safety of Care groups, 48 were safety-net hospitals, 68 were CAHs, and 16 were specialty hospitals. However, the TEP still recommended this change because Mortality and Safety of Care are aspects of quality that are most important to patients and reflective of performance

[261] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[262] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[263] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[264] Centers for Medicare & Medicaid Services. (2017, December 20). Quarterly Updates and Specifications Report (v2.3). Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[265] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[266] Ibid.

[267] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 50496 (Aug 19, 2013) (to be codified at 42 CFR parts 412, 413, 414, 419, 424, 482, 485, and 489).

under a hospital's control.[268] Once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the star rating calculation.

We invite public comment on our proposals to require that hospitals must report at least three measures groups, one of which must specifically be the Mortality or Safety of Care outcome group, each with at least three measures. Once this reported threshold is met, any additional measures and measure groups would contribute to hospital star ratings. We also propose to codify these policies at § 412.190.

7. Proposed Approach to Peer Grouping Hospitals

a. Background

We have not previously grouped hospitals by peers within the Overall Star Rating methodology. However, as part of our discussion with stakeholders about the comparability of the Overall Star Rating, peer grouping and potential peer grouping variables were discussed in two TEP meetings (March 2018,[269] and November 2019[270]), two Provider Leadership Work Group meetings (February and November 2019), two Patient & Advocate Work Group meetings (December 2017 and October 2019), and presented during two public comment periods (August 2017[271] and March 2019[272]). Through stakeholder engagement activities, we presented data on peer grouping variables including number of measures or measure groups a hospital reports, teaching designation, specialty designation, critical access designation, and number of beds at a hospital, among others. While there was no consensus among stakeholders regarding which hospital characteristic variable would be most appropriate for peer grouping,[273] CMS focused on the number of measure groups reported as a peer grouping variable based on analyses for many possible variables that assessed similarities among hospitals within peer groups and predictability of hospitals assignments to peer groups over time. Larger hospitals, for example, generally submit the most measures and smaller hospitals submit the fewest. Peer grouping by number of measure groups provides alignment with hospital size.

b. Proposed Peer Grouping

In this proposed rule, for Overall Star Rating beginning with CY 2021 and subsequent years, we propose to group hospitals that provide acute inpatient and outpatient care by the number of measure groups for which they have at least three measures as shown in Figure 2. Specifically, after the minimum reporting thresholds are applied, hospitals would be grouped into one of three peer groups based on the number of measure groups for which they report at least three measures—three measure groups, four measure groups, and five measure groups. Once grouped, k-means clustering would be applied within each peer group to assign hospital summary scores to star ratings. We also propose to codify this policy at § 412.190.

[268] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[269] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

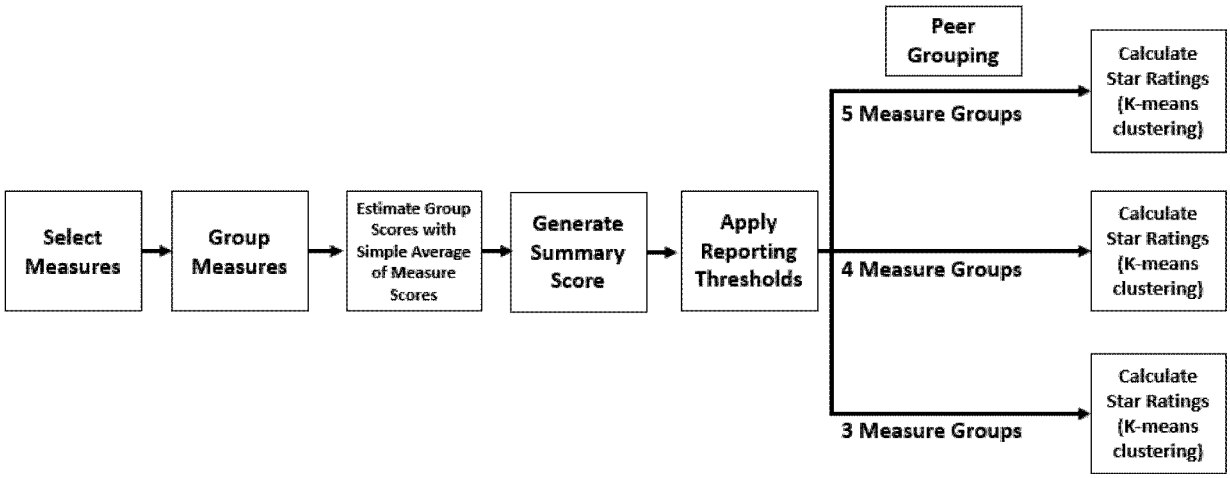
[270] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[271] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[272] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[273] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

Figure 2. Approach to Peer Grouping



Peer grouping hospitals based on the number of measure groups for which they report at least three measures is responsive to stakeholder concerns about the comparability of hospital star ratings and allows hospitals to be assigned to star ratings relative only to other similar hospitals in the same peer group.

We propose to group hospitals by measure group reporting to capture key differences that are important to stakeholders, such as differences in size, patient volume, case mix,[274] and services provided (service mix [275]). For example, larger hospitals with more diverse case mix and service mix, such as large urban teaching hospitals, report a greater number of measures, and therefore measure groups, and would be grouped separately from smaller hospitals with less diverse patient cases and service mix, which tend to report fewer measures and measure groups.

Hospital summary scores would be placed into three peer groups after calculation of the weighted average of measure group scores and before the assignment of hospitals to star ratings using k-means clustering.[276] This proposal is dependent on a sufficient number of hospitals that provide acute inpatient and outpatient care reporting three, four, and five measure groups to form the three peer groups. We simulated effects of this policy based on January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*): 348 (10 percent) hospitals reported at least 3 measures in 3 groups, 583 (17 percent) reported 4 groups, and 2,509 (73 percent) reported all 5 groups. These group sizes were vetted with the TEP [277] and workgroups and considered adequately sized for clustering into peer grouped star ratings.

Of note, this proposal is contingent on the participation of CAHs, as outlined in section B.2. Proposal to Continue to Include Critical Access Hospitals in the Overall Star Rating, since CAHs make up approximately half of the hospitals in the three measure group peer group and their exclusion from the Overall Star Rating would not produce peer groups with a sufficient amount of hospitals for comparison. Because many CAHs currently report the minimum three measure groups required by the reporting threshold, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating, and make up approximately half of the hospitals within the three measure group peer group, there would likely be an insufficient number of hospitals in the three measure group peer group to produce adequate variation through k-means clustering [278] if CAHs were not included in the calculation. If CAHs were not included, the difference in summary score between a two-star and three-star hospital may be modest and not truly reflective of differences in hospital quality.

After peer grouping, we would then assign star ratings using k-means clustering [279] (discussed in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this proposed rule) among hospitals within a single group, that is, relative only to hospitals in the same group. Specifically, hospitals would be grouped based on whether they have at least three measures for three measure groups, four measure groups, or five measure groups. The approach to peer grouping would retain the method used for assigning star ratings. Currently, the Overall Star Rating methodology uses a k-means clustering algorithm to assign hospitals to one of five star rating categories based on the distribution of hospital summary scores. This method aims to make hospital summary scores more similar within one star rating category and more different than hospital summary scores in other star rating categories. The proposed approach to peer grouping would be to also apply k-means clustering [280] to assign hospitals to one of five star ratings based only on hospitals in that peer group. For example, hospitals with three measure groups would be assigned to star ratings based on their summary score relative to other hospital summary scores with three measures groups, but not with respect to hospital summary scores among hospitals with four or five measure groups. Since hospitals in a peer group are being compared only to each other and k-means clustering is a comparative approach to assigning star ratings,[281] hospitals with the same summary score but different peer groups could receive different star ratings. In other words, a hospital with three measure groups could have the same summary score as a hospital with four measure groups; however, that summary score could fall within the four-star cluster for the three measure group peer group and the five-star cluster for the four measure group peer group. In addition, peer grouping hospitals would increase the comparability of star ratings within peer groups but decrease the comparability of star ratings across peer groups for patients. For example, once summary scores are calculated through the weighted average of measure group scores, a hospital within the three measure group peer group would not be assigned to a star rating relative to hospitals within the four or five measure group peer groups in the same geography or service line to whom that hospital is being compared by patients and consumers.

Applying peer grouping after the calculation of summary scores and before the assignment of hospitals to star ratings, allows: (1) Hospital summary scores to be equivalent and comparable among all hospitals, regardless of peer grouping; (2) transparency and the ability for stakeholders to review measure group and summary score results comparable to all other hospitals in the nation for quality improvement efforts within their confidential hospital-specific reports during the 30-day confidential preview period or the *Hospital Compare* or its successor websites' downloadable database upon public release; (3) minimal sensitivity of measure-level differences between peer groups on star ratings; and (4) hospitals' final star ratings to only be in comparison to ''like'' hospitals that have a similar number of measure groups.

We have conducted several analyses to inform decision making regarding peer grouping. To determine whether peer grouping not only supports CMS efforts to improve the comparability of star ratings, but also the predictability of hospital assignments to peer groups, we simulated potential effects of this proposal and assessed the stability of peer groups over time. Hospitals tend to report the same number of measure groups over time and therefore are often assigned to the same peer group each reporting period. Using historical data over five previous years, hospitals would have been assigned to the same peer groups of three, four, or five measure groups 96 to 98 percent of the

[274] Centers for Medicare & Medicaid Services. (2019). *Frequently Asked Questions for the Risk-Standardized Outcome and Payment Measures.* Retrieved from *qualitynet.org: https://www.qualitynet.org/files/5d0d374c764be766b010136d?filename=2019_IQR_CBMsrs_FAQs.pdf.*

[275] Ibid.

[276] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[277] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[278] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[279] Ibid.

[280] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[281] Ibid.

time, indicating a high level of consistency over time. Furthermore, peer grouping hospitals based on the number of measure groups for which they report at least three measures creates similar within peer group hospital reporting profiles. Using January 2020 reporting data (from October 2019 publicly reported measure data on *Hospital Compare*), hospitals with three measure groups tend to almost always report at least three measures in the Mortality (86 percent), Readmission (86 percent), and Timely and Effective Care (96 percent) measure groups but tend to seldom report at least three measures in the Safety of Care (15 percent) and Patient Experience (17 percent) measures groups. Hospitals with four measure groups tend to always report at least three measures in the Readmission (100 percent) measure group, tend to almost always report at least three measures in the Mortality (92 percent), Patient Experience (98 percent), and Timely and Effective Care (99 percent) measure groups, and tend to seldom report at least three measures in the Safety of Care (11 percent) measure group. Hospitals with five measure groups report at least three measures in all five measure groups. Hospitals with three and four measure groups are more likely to be critical access hospitals (58 percent in the peer group with three measure groups and 52 percent in the peer group with four measure groups) while hospitals in the peer group with five measure groups tend to be safety-net (19 percent of the peer group) and teaching (56 percent of the peer group) hospitals. These results confirm that peer grouping results in the grouping of hospitals with similar reporting profiles and characteristics and may address stakeholder concerns about the comparability of hospital star ratings.

Peer grouping hospitals by the number of measure groups for which they report at least three measures for the assignment of hospital summary scores to star ratings addresses stakeholder concerns about the comparability of hospitals with fundamental differences, such as measure reporting, hospital size or volume, patient case mix, and service mix. However, we note that peer grouping hospitals would decrease the comparability of all hospitals for patients and change the historical, conceptual comparative nature of the Overall Star Rating.

In developing our proposal, we also considered not peer grouping and continuing to apply k-means clustering amongst all hospitals meeting the minimum reporting thresholds to assign hospitals to star ratings. However, we ultimately decided to propose to peer group hospitals based on the number of measure groups to be responsive to stakeholder feedback and increase comparability of hospital star ratings. Should we not finalize our proposal to include CAHs, we will not peer group the Overall Star Rating by number of measure groups.

We invite public comment on our proposal to peer group hospitals by number of measure groups and to codify this policy at § 412.190.

8. Step 6: Application of Clustering Algorithm To Assign Star Rating

a. K-Means Clustering

(1) Current Application of K-Means Clustering

In the past, in order to assign hospitals to star ratings, we used an approach called k-means clustering to categorize hospitals' summary scores. K-means clustering is a clustering algorithm that groups entities, in this case hospitals, into a specified number of categories,[282] in this case five star rating categories in which one star is the lowest and five stars is the highest, by grouping values, in this case hospital summary scores, so that they are more similar within groups and more different between groups. In other words, for each publication of the Overall Star Rating, k-means clustering establishes cutoffs, or a range of summary scores, for each of the star rating categories so that summary scores in one star rating category would be more similar to each other and less similar to summary scores in other star rating categories.

We considered multiple approaches to assigning hospitals to star ratings, including percentiles, statistically significant cutoffs, and clustering algorithms. Each option was presented to the TEP [283] [284] and during a public input period [285] by the Overall Star Rating development contractor. While any approach to assigning hospitals to star ratings will result in some hospitals with summary scores near the cutoffs of two star rating categories, at that time, we chose to use k-means clustering because it applied a data-driven approach to specification of five categories, minimized the within-category differences and maximized the between-category differences in summary scores, and was similar to the clustering algorithm used to calculate the HCAHPS Star Rating.[286] Stakeholders have generally supported the use of k-means clustering to assign star ratings over arbitrary percentiles and statistically significant cutoffs.[287] [288] [289]

In December 2017, we applied a minor update to the application of k-means clustering by running the summary scores through the clustering algorithm multiple times, a statistical method called complete convergence,[290] to provide more reliable and stable star rating assignments. Prior to December 2017, we performed Winsorization [291] of hospital summary scores to limit the influence of extreme outliers. Winsorization is a common strategy used to set extreme outliers to a specified percentile of the data.[292] While k-means clustering has been used within the methodology since implementation in July 2016, the update to run k-means clustering to complete convergence results in a broader distribution of star ratings and negates the need for Winsorization of hospital summary scores.[293]

(2) Proposal To Continue K-Means Clustering

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose to continue use k-means clustering with

[282] Ibid.

[283] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[284] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[285] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[286] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings* . Retrieved from *www.hcahpsonline.org*: *https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[287] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[288] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[289] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[290] Hsu, P.L., & Robbins, H. (1947). Complete Convergence and the Law of Large Numbers. *Proceedings of the National Academy of Sciences of the United States of America, 33*(2), 25–31. doi:10.1073/pnas.33.2.25.

[291] Kwak, S.K., & Kim, J.H. (2017, July 27). ''Statistical data preparation: management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[292] Ibid.

[293] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

complete convergence without Winsorization of hospital summary scores, to group hospitals into five clusters to assign star ratings so that one star is the lowest and five stars is the highest. We also propose to codify this policy at § 412.190. We believe use of k-means clustering is most appropriate because it aligns with the clustering algorithm used for the HCAHPS Star Rating [294] and maximizes the within star rating category similarities and between star rating category differences. We seek public comment on our proposal to continue to use k-means clustering to complete convergence to assign hospitals to star ratings, where one star is the lowest and five stars is the highest, and to codify this policy at § 412.190

F. Preview Period

1. Background

In the past, similar to the process in place for multiple CMS quality programs prior to public reporting of measure scores, hospitals providing acute inpatient and outpatient care that are included in the Overall Star Rating had the opportunity to confidentially review their star rating as well as the measures and measure group scores that contribute to their star rating during the confidential preview period a few months prior to the public release of the Overall Star Rating. We provided hospitals with a confidential report and at least 30 days to preview their results prior to releasing the Overall Star Rating. During the confidential preview period, hospitals received a confidential hospital-specific report (HSR), which detailed their measure performance and measure group scores with comparisons to the national average, as well as their summary score and star rating. The HSRs also provided information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. The Overall Star Rating preview period allowed hospitals to review, understand, and ask CMS questions about how the star rating was calculated.

2. Proposed Preview Period

In this proposed rule, for Overall Star Rating beginning with the CY 2021 and subsequent years, we propose to continue our current process regarding the preview period. Specifically, a few months prior to public release of the Overall Star Rating, we would issue a confidential HSR, which would detail measure and measure group scores as well as their summary score and star rating. The HSRs would also provide information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. During this preview period, hospitals would have at least 30 days to preview their results, and if necessary, reach out to CMS via the QualityNet Question and Answer tool, or additional contact information provided within preview period resources with questions about the methodology and their star ratings results. We also propose to codify this policy at § 412.190. This proposal as well as the proposal to report Overall Star Rating annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year would allow hospitals more time to review and understand the methodology and their results, as well as reach out with questions.

We invite public comment on our proposals to: (1) Establish a 30-day confidential preview period, and (2) codify the confidential preview period at § 412.190.

G. Overall Star Rating Suppressions

In this proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we propose separate suppression policies for subsection (d) hospitals and CAHs given that subsection (d) hospitals are subject to CMS quality programs and CAHs voluntarily submit measure data.

1. Subsection (d) Hospitals

a. Background

In the past, we would have only suppressed Overall Star Rating for subsection (d) hospitals when there were errors within the Overall Star Ratings calculation or the calculation for individual measures, which would first need to be addressed through CMS programs prior to recalculating Star Ratings. Furthermore, there is currently no specific corrections process for the Overall Star Rating.

b. Proposed Suppression

In this proposed rule, we propose to continue to allow for suppression, but only in limited circumstances. Specifically, for the Overall Star Rating beginning with the CY 2021 and subsequent years, we propose to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when:

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calcualtions that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data.

We also propose to codify this policy at § 412.190.

As mentioned above, consistent with past practices, we propose that we would not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (for example, authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. We note that the Overall Star Rating is calculated using individual measures publicly reported on *Hospital Compare* or its successor site via CMS quality programs. Hospitals can utilize established processes under each program in order to review and correct individual measure scores. As policies are specific to each program, we refer readers to the respective hospital program's policies. We also refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information. We invite public comment on our proposals as discussed above.

(1) CAHs

(a) Background

As discussed in section B. Critical Access Hospitals in the Overall Star Rating of this proposed rule, CAHs voluntarily submit measure data consistent with certain CMS programs. These measure results are then publicly reported on *Hospital Compare* or its successor websites. In the past, since the Overall Star Rating summarizes available measure information on *Hospital Compare* or its successor

[294] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org*: *https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

website, CAHs with publicly reported measures results on *Hospital Compare* that also met the reporting thresholds to receive a star rating were assigned a star rating.

CAHs that did not want their voluntarily submitted measure data publicly reported on *Hospital Compare* could submit a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' available on QualityNet) per the forms' instructions during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Ratings. We note that this preview period is distinct from the Overall Star Rating preview period. If the measure data itself was withheld on *Hospital Compare,* it subsequently could not be included in the Overall Star Rating. Generally, upon public release of the Overall Star Rating, we also provide a public input file containing aggregate hospital measure scores, measure group scores, and summary scores along with the Overall Star Rating SAS pack for transparency and to allow stakeholders the opportunity to replicate the calculation of star ratings. If a CAH withheld its data from *Hospital Compare* at this stage, that data was excluded from both the Overall Star Rating calculation and the public input file.

Furthermore, because CAHs voluntarily reported measures, CAHs that would otherwise receive an Overall Star Rating could request to withhold their star rating during the Overall Star Rating preview period. However, at this stage, individual measure scores were still included in the public input file due to time and process constraints.

(b) Proposed Withholding

In this proposed rule, for Overall Star Rating beginning in CY 2021 and subsequent years, we propose to (1) continue to allow CAHs to withhold their Overall Star Rating; and (2) to codify this at § 412.190. These proposals, discussed in more detail below, align with the guiding principles of transparency and inclusivity of hospitals, as outlined within section A. Background, while allowing CAHs to voluntarily withhold their Overall Star Rating.

i. Withholding Star Ratings

Beginning with CY 2021 and for subsequent years, we propose that CAHs may request to withhold their Overall Star Rating from public release on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period as proposed in section F.2. Proposed Preview Period of this proposed rule. We also propose to codify this policy at § 412.190. CAHs may make this request by submitting the ''Request Form for Withholding/Footnoting Data for Public Reporting'' form [295] available on QualityNet by midnight of the last day of the Overall Star Rating preview period. This is the same form used for withholding data from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor website through completion of this form, all of their measures scores will be withheld from the Overall Star Rating calculation. However, individual measure scores would still be included in the public input file. By the time the Overall Star Rating preview period begins, there would not be sufficient time for CMS to remove a CAH's data from the public input file and then recalculate the Overall Star Rating for all affected hospitals. As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor website using October 2020 data, CAHs would need to submit their withholding request during the Overall Star Rating preview period, which would occur a few months prior to the January 2021 publication, in order to withhold their Overall Star Rating (but their data would still remain in the Public Input File).

ii. Withholding Star Ratings and Public Input File Data

In addition, we propose that CAHs may request to have their Overall Star Rating withheld from public release on *Hospital Compare* or its successor website, as well as their data from the public input file, which is posted upon the public release of the Overall Star Rating and used by stakeholders to replicate the calculation of star ratings, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Ratings. We also propose to codify this policy at § 412.190. As an example, we refer readers to our discussion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608) for more information about this preview period in one of CMS' quality programs. CAHs may request that CMS withhold their measure and star rating results from public posting on *Hospital Compare* or its successor website and the Overall Star Rating public input file by submitting a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' [296] available on QualityNet) per the forms' instructions. This is the same form used for withholding from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor website through completion of this form during this stated timeframe, all of their measures scores would be withheld from the Overall Star Rating calculation and public input file.

As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor website using October 2020 data, CAHs would need to submit their withholding request during the CMS quality program-level 30-day confidential preview period, which would generally occur a few months prior to the October 2020 *Hospital Compare* refresh in order to withhold both their Overall Star Rating and data from the public input file.

We invite public comment on our proposals.

XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[297] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In addition to codifying the basis and scope of subpart I, Prior Authorization for Outpatient Department Services, the regulations include definitions associated with the prior authorization process, provide that prior authorization must be obtained as a condition of payment for the listed service categories, and include the process by

[295] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

[296] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

[297] See also Correction Notice issued January 3, 2020 (85 FR 224).

which hospitals must obtain prior authorization. Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained, which are: (i) Blepharoplasty, (ii) Botulinum toxin injections, (iii) Panniculectomy, (iv) Rhinoplasty, and (v) Vein ablation. Paragraph (b) states that CMS will update this list through formal notice-and-comment rulemaking, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of Two New Service Categories

In accordance with § 419.83(b), we propose to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also propose to add those service categories to § 419.83(a). We propose that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. As explained more fully below, the proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) and is based upon our determination that there has been an unnecessary increase in the volume of these services. Based on the different implementation dates for the original five service categories and the two proposed service categories, we propose to add a reference to the July 1, 2020 implementation date to the end of paragraph (a)(1) to reflect the implementation date for the original five service categories. Specifically, we propose that paragraph (a)(1) would read, ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020.'' We also propose to add a new paragraph (a)(2), which would read: ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021.'' We propose that the two proposed service categories would be added as new subparagraphs to new paragraph (a)(2) as follows: (i) Cervical Fusion with Disc Removal and (ii) Implanted Spinal Neurostimulators. We also propose that existing paragraph (a)(2) would be renumbered as paragraph (a)(3).

We propose that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 53. For ease of review, we are only including in Table 53 the CPT codes that fall into the two proposed service categories in proposed new § 419.83(a)(2)(i) and (ii). Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1). For ease of reference, we have included the Final List of Outpatient Services that Require Prior Authorization for the five initial service categories in Table 54.[298] Again, the prior authorization process for the two proposed additional service categories would be effective for dates of service on or after July 1, 2021.

2. Basis for Proposing To Add Two New Service Categories

As part of our responsibility to protect the Medicare Trust Funds, we are continuing our routine analysis of data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

As we noted in the CY 2020 OPPS/ASC proposed rule,[299] we recognize the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted and the average annual rate-of-increase in the Medicare allowed amounts. For this proposed rule, we updated the analyses undertaken for the CY 2020 OPPS/ASC proposed rule.[300] In proposing the addition of these two service categories, we reviewed over 1.2 billion claims related to OPD services during the 12-year period from 2007 through 2018.[301] We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 2.8 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 117 million claims submitted for payment in 2018. The 2.8 percent rate reflects a slight decrease when compared to the 3.2 percent rate identified in the CY 2020 OPPS proposed rule. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 7.8 percent. Again, this is a slight decrease when compared to the 8.2 percent rate identified in the CY 2020 OPPS/ASC proposed rule. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $68 billion in 2018, while during this same 12-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.9 percent.

Below we describe what we believe are the unnecessary increases in volume for each of the categories of services for which we propose to require prior authorization.

- *Implanted Spinal Neurostimulators:* Our analysis of IDR data showed that, with regard to Implanted Spinal Neurostimulators, claims volume for insertion or replacement of spinal neurostimulator pulse generator or receiver, 63685, increased by 174.6 percent between 2007 and 2018, reflecting a 10.2 percent average annual increase, a significantly greater annual increase than the 2.8 percent average annual increase for all OPD services. From 2016 through 2018, the average annual increase in volume was 17 percent. For 63688, revision or removal of implanted spinal neurostimulator pulse generator or receiver, we observed an increase of 149.7 percent between 2007 and 2018, reflecting a 8.8 percent average annual increase, and for 63650, implantation of spinal neurostimulator electrodes, accessed through the skin, we observed an increase in volume of 77.9 percent between 2007 and 2018,

[298] The table appears on pages 61456 and 61457 of the Final Rule but contains certain technical errors. The table printed here is consistent with our January 3, 2020 correction notice. See 85 FR at 225.

[299] *See* Hospital Outpatient Prospective System/Ambulatory Surgical Center Payment System Proposed Rule, 84 FR 39398 at 39603 (August 9, 2019).

[300] 84 FR 39604.

[301] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

which was an average annual increase of 6.5 percent, these average annual increases for both codes are higher than the 2.8 percent average annual increase for all OPD services over the same period. When analyzing these data, we fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the 63650 code, which did not show a corresponding claims volume change that would explain the large increases noted over time when compared to the rates of change for all OPD services.

• *Cervical Fusion with Disc Removal:* When reviewing CMS data available through the Integrated Data Repository (IDR), we determined that claims volume for the initial level of spinal fusion of the cervical spine with removal of the corresponding intervertebral disc, CPT® [302] code 22551, had increased by 1,538.9 percent between 2012 and 2018, reflecting a 124.9 percent average annual increase, a substantially greater increase than the 2.8 percent average annual increase for all OPD services over the same period and the 2.1 percent average annual increase for all OPD services from 2007 through 2018. In fact, the increase between 2016 and 2018 for this code was 736 percent. The add-on code, 22552 (for additional levels), reflected claims volume increases of 3,779.6 percent between 2012 and 2018, reflecting a 174.9 percent average annual increase, again, far eclipsing the 2.8 percent average annual increase for all OPD services. Between 2016 and 2018 alone, the claims volume for this code increased 1,020 percent. These codes were first used in 2011 to better reflect the combination of the cervical fusion and the disc removal procedures. Accordingly, we use data from 2012 forward to allow for the start-up statistics to normalize. Nonetheless, the dramatic increases in volume that we have identified persisted well after the initial use of these codes.

A rate of increase higher than the expected rate is not always improper; however, when we considered the data, we believe the increases in the utilization rate for this service are unnecessary. CPT 22551 began being used in 2011. The use of the code almost tripled in 2012 and significantly increased each year thereafter. The increases became even more dramatic beginning in 2016, when the ambulatory payment classification (APC) for CPT 22551 was changed to a higher level. Effective January 1, 2016, the CY 2016 OPPS/ASC final rule [303] moved the APC for CPT 22551 from APC 0208 (Laminectomies and Laminotomies) to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis). APC 0425 has a higher payment than APC 0280, the group to which they were originally assigned. APC 0208 had a geometric mean cost of $4,267, but APC 0425 had a geometric mean cost of $10,606. This represents a 149 percent increase in allowed amount as a result of the move to APC 0425, which may have contributed to the unnecessary increase in volume. Again, this represents a 736 percent increase in claims volume between 2016 and 2018 when all outpatient department services demonstrated an 0.4 percent increase overall for the same time period. We believe that the change in the payment rate likely prompted the unnecessary volume increases and may have created a financial motivation to utilize these codes more than may be considered medically necessary. We believe prior authorization is an appropriate control method for the unnecessary increase in volume for this service.

Our conclusion that the increases in volume for both Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators are unnecessary is based not only on the data specific to each service category, but also on a comparison of the rate of increase for the service categories to the overall trends for all OPD services. We believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. For both services categories, we researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe the increases were necessary. Moreover, other than the recent changes in the CPT code and APC assignments described above, CMS has not taken any action that would explain the significant increases identified. We also conducted reviews of clinical and industry-related literature and found no indication of changes that would justify the increases observed. After reviewing all available data, we found no evidence suggesting other plausible reasons for the increases, which we believe means financial motivation is the most likely cause. We believe utilizing codes because of financial motivations, as opposed to medical necessity reasons, has resulted in an unnecessary increase in volume. Therefore, comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, and prior authorization is an appropriate method to control these volume increases.

We continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We request comments on the addition of these two service categories.

BILLING CODE 4120–01–P

[302] The Current Procedural Technology (CPT) coding system is a registered trademark of the American Medical Association.

[303] 79 FR 66769 and 80 FR 70297.

TABLE 53: 2021 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

	Beginning for service dates on or after July 1, 2021
Code	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

TABLE 54: 2020 FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

	Beginning for service dates on or after July 1, 2020
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk

Code	(iv) Rhinoplasty, and related services[304]
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

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XVIII. Clinical Laboratory Fee Schedule: Proposed Revisions to the Laboratory Date of Service Policy

A. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the laboratory test is ordered, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected. In that final rule, we also established a policy that the DOS for laboratory tests that use an archived specimen is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134, which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered ''archived.'' In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered ''archived,'' in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an ''archived'' specimen as a specimen that is stored for more than 30 calendar days before testing. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

[304] Code 21235, ''Obtaining ear cartilage for grafting'' was removed on June 10, 2020 in accordance with § 419.83(d). See CMS *http://go.cms.gov/OPD_PA.*

B. Medicare DOS Policy and the ''14-Day Rule''

In the final rule with comment period entitled, in relevant part, ''Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B'' published in the **Federal Register** on December 1, 2006 (December 1, 2006 MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in that MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure) is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even when the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the December 1, 2006 MPFS final rule, we established these five criteria, which we refer to as the ''14-day rule,'' to distinguish laboratory tests performed as part of posthospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the December 1, 2006 MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine posthospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the December 1, 2006 MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B; that is, separate from the payment for hospital services.

C. Billing and Payment for Laboratory Services Under the OPPS

As noted previously, the DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. Separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we refer to as the ''under arrangements'' provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does not meet the DOS requirements in § 414.510(b)(2)(i), (b)(3), or (b)(5), the DOS would be the date the specimen was collected from the patient. In that case, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In previous rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350 and 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we package most CDLTs under the OPPS. However, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70348 through 70350), we excluded all molecular pathology laboratory tests from packaging because we believed

these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We stated that we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that meet one of the four criteria above and that are listed on the CLFS are paid under the CLFS, rather than being packaged and paid for under the OPPS.

D. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of Public Law 113–93, the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule'' (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the Food and Drug Administration.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the June 23, 2016 CLFS final rule (81 FR 41076 through 41083). For additional information regarding ADLTs, we refer readers to the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html*.

E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59393 through 59400), we established an additional exception at § 414.510(b)(5) so that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under the exception that we finalized at § 414.510(b)(5), in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59397), we explained that we believed the laboratory DOS policy in effect prior to CY 2018 created administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We noted that under the laboratory DOS policy in effect prior to CY 2018, if the tests were ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories generally could not bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital had to bill Medicare for the test, and the laboratory had to seek payment from the hospital. We noted that commenters informed us that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. The commenters also stated that as a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we noted that we had heard from commenters that the laboratory DOS policy in effect prior to CY 2018 may have disproportionately limited access for Medicare beneficiaries under Medicare Parts A and B, because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognized that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the DOS policy in effect prior to CY 2018. We noted that we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, and we had already established exceptions to the DOS policy that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We stated that we believed a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging policy, which we understood are used to guide and manage the patient's care after the patient is discharged from the hospital

outpatient department. We noted that we believed that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, we reiterated that these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agreed with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, we issued Change Request (CR) 10419, Transmittal 4000, the claims processing instruction implementing the laboratory DOS exception at § 414.510(b)(5), with an effective date of January 1, 2018 and an implementation date of July 2, 2018. After issuing CR 10419, we heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing the DOS exception set forth at § 414.510(b)(5). On July 3, 2018, we announced that, for a 6-month period, we would exercise enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5). We explained that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established by CR 10419, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the exception. We noted that this enforcement discretion would apply to all providers and suppliers with regard to ADLTs and molecular pathology tests subject to the laboratory DOS exception policy, and that during the enforcement discretion period, hospitals may continue to bill for these tests that would otherwise be subject to the laboratory DOS exception.

We then extended the enforcement discretion period for two additional, consecutive 6-month periods, after learning that there were still many entities needing additional time to come into compliance. The final enforcement discretion announcement as well as CR 10419, Transmittal 4000 is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html.* The enforcement discretion period ended on January 2, 2020.

During the period of enforcement discretion, we continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). In particular, we heard from stakeholders that some entities performing molecular pathology testing subject to the laboratory DOS exception, such as blood banks and blood centers, may not be enrolled in the Medicare program and may not have established a mechanism to bill Medicare directly. In the CY 2020 OPPS/ASC proposed rule (84 FR 39603), we sought comments on excluding blood banks and blood centers from the laboratory DOS exception at § 414.510(b)(5). Based on concerns raised by stakeholders, we stated that we believe blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. Given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, we questioned whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. We stated that we were concerned that our current policy may unbundle molecular testing performed by a blood bank or center for a hospital patient.

For these reasons, and based on the support received from commenters, in the CY 2020 OPPS/ASC final rule (84 FR 61444), we finalized a revision to the laboratory DOS policy to exclude molecular pathology tests when performed by laboratories that are blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). We also finalized a definition for ''blood bank or center'' at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

A list of the specific laboratory tests currently subject to the laboratory DOS exception at § 414.510(b)(5) is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html.*

F. Proposed Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61438 through 61439), we explained that protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) that are not considered molecular pathology tests and are not designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, are packaged under the OPPS at this time. Though they do not currently qualify for the DOS exception at § 414.510(b)(5) solely because they are MAAAs, we noted that several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service.

In particular, stakeholders have suggested that certain protein-based MAAAs, specifically, those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as other tests that are not paid under the OPPS and are paid separately under the CLFS, and so should be treated similarly (82 FR 59299). Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. Notably, with one exception (CPT code 81490), each of those tests described by the CPT codes identified by stakeholders is a cancer-related protein-based MAAA. We did not establish an exception to the laboratory DOS policy for protein-based MAAAs in the CY 2020 OPPS/ASC final rule with comment period, but we did note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the DOS exception at § 414.510(b)(5). We indicated in that rule that we intended to consider policies regarding the application of the DOS policy to MAAAs for future rulemaking (84 FR 61439).

After further consideration of this issue, we now believe certain MAAAs, specifically, cancer-related protein-based MAAAs, which stakeholders identified, as discussed above, have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine posthospital care. As we explain below, we believe these tests are distinguishable from the care the patient receives in the hospital,

similar to molecular pathology tests and tests designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, which are currently excluded from the OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5). Therefore, we propose to exclude cancer-related protein-based MAAAs from the OPPS packaging policy, as discussed in section II.a.3. of this proposed rule, and create an exception to the laboratory DOS rule for them. These proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5).

We understand that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of an ADLT in § 414.502, cancer-related protein-based MAAAs are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department because the test results are used to determine potential future oncologic surgical and chemotherapeutic interventions; they would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. In other words, decisions as to particular therapies and/or surgical procedures, as guided by the results of the test, are not made during the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we propose to add cancer-related protein-based MAAAs to our current laboratory DOS exception rule at § 414.510(b)(5). Under this proposed revision, the DOS for a cancer-related protein-based MAAA would be the date the test was performed if: (1) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2); (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness.

This proposed revision to our laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs, that are excluded from the OPPS packaging policy and meet the DOS requirements at § 414.510(b)(5), to bill Medicare directly for those tests instead of seeking payment from the hospital. Similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of ADLT in § 414.502, we believe that cancer-related protein-based MAAAs are distinguishable from the care the patient receives during the primary hospital outpatient encounter because, as noted above, the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Therefore, were we to finalize our proposal, we believe we would not be unbundling laboratory tests that are appropriately associated with the primary hospital outpatient service.

As discussed in section II.a.3. of this proposed rule, the AMA CPT 2020 manual describes a MAAA, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' Further, the code descriptors of MAAAs include several specifics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). As the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types and provides information regarding the material(s) analyzed, the AMA CPT manual is a useful tool to identify cancer-related MAAAs that are ''protein-based''. Accordingly, using the AMA CPT 2020 manual criteria to identify a MAAA that is cancer-related, and, of those tests, identifying the ones whose analytes test proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. We note that CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018, and therefore, is currently already subject to the laboratory DOS exception in § 414.510(b)(5). Therefore, the cancer-related protein-based MAAAs that would be excluded from the OPPS packaging policy and subject to an exception from the laboratory DOS policy under our proposals are CPT codes 81500, 81503, 81535, 81536 and 81539. These tests have not been designated by CMS as ADLTs under paragraph (1) of the definition of ADLT in § 414.502 and so are not currently subject to the laboratory DOS exception in § 414.510(b)(5). We would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

XIX. Physician-Owned Hospitals

A. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the ''rural provider exception''). In order to qualify for the rural provider exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act), substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area, and, in the case where the entity is a hospital, the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the ''whole hospital exception''). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the

hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

B. Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as an ''applicable hospital.'' Section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as either an ''applicable hospital'' or a ''high Medicaid facility.'' These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2) and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An applicable hospital means a hospital: (1) That is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and (v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. CMS has identified in regulation at § 411.362(c)(2)(ii), (iv), and (v) acceptable data sources for determining whether a hospital qualifies as an applicable hospital. A ''high Medicaid facility'' means a hospital that: (1) Is not the sole hospital in a county; (2) with respect to each of the 3 most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. CMS has identified in regulation at § 411.362(c)(3)(ii) acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility. In the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the process for a hospital to request an exception from the prohibition on facility expansion (the exception process) and related definitions at § 411.362(c) and § 411.362(a), respectively (76 FR 74122).

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception to the prohibition on expansion of facility capacity up to once every 2 years. In the CY 2012 OPPS/ASC final rule, we extended this provision to high Medicaid facilities using our authority under sections 1871 and 1877(i)(3)(A)(1) of the Act (76 FR 74525). We stated that, although the statute provides that an applicable hospital may request an exception up to once every 2 years, we believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years (while also limiting its total growth) balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the exception to the prohibition on expansion of facility capacity (76 FR 74524). We did not receive any public comments regarding the frequency of exception requests. Under current § 411.362(c)(1), both applicable hospitals and high Medicaid facilities may request an exception to the prohibition on expansion of facility capacity up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we adopted a parallel limit in the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity (76 FR 74524). There, we noted that, in response to our request for comment on whether the 200 percent limit would be sufficient to balance the intent of the general prohibition on facility expansion with the purpose of the exception process, which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated, commenters supported our proposal regarding the amount of permitted increase and at least one commenter specifically supported the parallel treatment of high Medicaid facilities (76 FR 74524). Under current § 411.362(c)(6)(i), a 200 percent limitation applies to both applicable hospitals and high Medicaid facilities.

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we extended this limitation on the location of expanded facility capacity to high Medicaid facilities, explaining that we believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process (76 FR 74524). We did not receive any public comments regarding the location of the permitted increase. Under current § 411.362(c)(6)(ii), expanded facility

capacity may occur only in facilities on the hospital's main campus.

In 2017, CMS launched the Patients over Paperwork initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. As part of this initiative, we reviewed the regulations at § 411.362(c) as they apply to high Medicaid facilities. Certain of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals and their extension to high Medicaid facilities was effectuated using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act. We continue to believe that our current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally. Nevertheless, the Congress did not mandate this treatment of high Medicaid facilities and, in light of the Patients over Paperwork initiative, we have reconsidered our policies. We believe that our current regulations impose unnecessary burden on high Medicaid facilities which, by definition, serve significant numbers of Medicaid patients relative to other hospitals in the counties in which they are located. Because the statute does not apply to high Medicaid facilities those requirements related to the frequency of permitted requests for exceptions to the prohibition on expansion of facility capacity, the total amount of permitted expansion of facility capacity, or the location of permitted expanded facility capacity, using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we propose to remove certain regulatory requirements for high Medicaid facilities that are not included in the statute.

We propose to revise § 411.362(c)(1) to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. To preserve CMS resources and to continue to maintain an orderly and efficient exception process, we propose that a high Medicaid facility may submit only one exception request at a time. Under proposed § 411.362(c)(1), a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision. We also propose to revise § 411.362(c)(6) with respect to high Medicaid facilities only to remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds and the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. Under proposed § 411.362(c)(6), these restrictions would apply only to applicable hospitals. We seek comment regarding our proposals.

Section 1877(i)(3)(A)(ii) requires CMS to provide an opportunity for community input when an applicable hospital applies for an exception to the prohibition on expansion of facility capacity. Through regulation, we made the community input opportunity applicable to facility expansion requests submitted by high Medicaid facilities (76 FR 74523). However, the statute does not expressly require CMS to furnish an opportunity for community input when a high Medicaid facility has applied for such an exception. Therefore, we are considering whether we should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. We are specifically interested in comments regarding the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high Medicaid facility seeking an exception to the prohibition on expansion of facility capacity. We are interested in comments regarding how CMS could obtain independent confirmation of the data provided by a high Medicaid facility in the absence of the community input opportunity (see 76 FR 74523). We note that obtaining independent confirmation of the data furnished by a high Medicaid facility could delay or add complexity to the review process. We solicit comments regarding whether the additional delay and complexity caused by the elimination of the community input opportunity for requests by high Medicaid facilities would result in greater burden or cause greater harm to high Medicaid facilities than continuing to permit community input on the expansion exception requests submitted by these hospitals.

C. Deference to State Law for Purposes of Determining the Number of Beds for Which a Hospital Is Licensed

In order to qualify for the rural provider or whole hospital exception to the physician self-referral law, a hospital may not increase the aggregate number of operating rooms, procedure rooms, and beds above that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless the Secretary has granted an exception to the prohibition on expansion of facility capacity under section 1877(i)(3) of the Act and § 411.362(c). The statute and our regulations refer to this number as the hospital's ''baseline number of operating rooms, procedure rooms, and beds.'' Thus, at the time a hospital wishes to qualify for the rural provider or whole hospital exception, it may not have an aggregate number of operating rooms, procedure rooms, and beds that exceeds its baseline number of operating rooms, procedure rooms, and beds (unless the Secretary has granted an exception).

Because the availability of the rural provider and whole hospital exceptions turns on whether a hospital has exceeded its baseline number of operating rooms, procedure rooms, and beds at the time of a physician's referral, a clear understanding of how to calculate the hospital's baseline number of operating rooms, procedure rooms, and beds is critical. Stakeholders have asked what CMS would consider the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement) under various State licensure schemes. We responded to formal advisory opinion requests in August 2019 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2019-01-Redacted.pdf*) and March 2020 (*https://www.cms.gov/files/document/cms-ao-2020-01.pdf*) regarding the inclusion of certain operating rooms, procedure rooms, and beds in a hospital's baseline number of operating rooms, procedure rooms, and beds. In March 2020, we also published a Frequently Asked Question addressing stakeholder inquiries regarding the determination of the number of beds for

which a hospital was licensed on March 23, 2010 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf*). The March 2020 Frequently Asked Question states:

Q: If a state's hospital licensure laws and regulations provide that a hospital may increase its licensed bed complement by a certain amount without prior approval of the state's licensing agency, what would CMS consider the number of beds for which the hospital was licensed on March 23, 2010 for purposes of section 1877(i)(1)(B) of the Social Security Act (the ''Act'') and 42 CFR 411.362(b)(2)?

A: As a general matter, neither section 1877 of the Act nor the physician self-referral regulations (42 CFR 411.350 through 411.389) preempt state licensure laws and regulations. In interpreting and applying the physician self-referral law, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. If the state would consider a bed to be ''licensed'' or within a hospital's ''bed complement'' on March 23, 2010, CMS would also consider the bed to be ''licensed'' or within a hospital's ''bed complement'' as of that date, regardless of the exact number printed on the hospital's physical license. To illustrate, assume that a state does not require prior approval from its licensing agency for a hospital to increase its bed complement by not more than ten beds or 10 percent of the total bed capacity, whichever is less, during a period of a license. However, the state requires notification of the change and that the hospital must at all times meet the physical plant, staffing, and all other requirements set forth in state law and regulations if additional beds are added. The license issued to the hospital on January 1, 2009 indicated that the hospital's bed complement was 100 beds. If the hospital increased its bed complement by 9 beds (to 109 beds) on January 1, 2010 and made no further changes to its bed complement prior to March 23, 2010, its baseline number of licensed beds on March 23, 2010 would be 109 for purposes of section 1877(i)(1)(B) of the Act and 42 CFR 411.362(b)(2), provided that the hospital made the appropriate notification to the state and the hospital at all times met the physical plant, staffing, and all other requirements set forth in state law and regulations after increasing its bed complement. The same would apply to any beds that a state considered to be licensed under its specific licensure scheme on March 23, 2010. Section 1877(i)(1)(B) of the Act limits the expansion of facility capacity of a hospital that wishes to qualify for the rural provider or hospital exceptions to the law's ownership or investment prohibition. (See section 1877(d)(2) and (3); 42 CFR 411.356(c)(1) and (3).) Specifically, section 1877(i)(1)(B) of the Act states that, among other things, to qualify for the rural provider or hospital exceptions, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010 is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. For purposes of applying this provision of the physician self-referral law, we refer to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 as the hospital's ''baseline.'' As stated above, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. However, in extraordinary circumstances, CMS may include additional beds when determining a hospital's ''baseline'' for purposes of section 1877 of the Act. See, for example, CMS–AO–2020–01 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions*). In order to ensure stakeholders' awareness of our interpretation regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), we propose to revise the definition of ''baseline number of operating rooms, procedure rooms, and beds'' at § 411.362(a) to include a statement that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State. We seek comment on our proposal to include this language in regulation text at § 411.362(a) generally, and specifically whether the inclusion of this language is necessary or could be perceived as inadvertently limiting the definition of ''baseline number of operating rooms, procedure rooms, and beds.''

XX. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2021, we are retaining these columns, updated to reflect the amount of the 2021 inpatient deductible. For CY 2021, we propose to add a new column to the OPPS Addenda, A, B, and C, entitled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31).

To view the Addenda to this proposed rule pertaining to proposed CY 2021 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''CMS–1736–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2021 NPRM OPPS Addenda'' at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2021 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''CMS–1736–P'' from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XXI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a

collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital IQR Program. We refer readers to the CY 2011 through CY 2020 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; and 84 FR 61468 through 61469, respectively) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109 which expires on March 31, 2023.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data (May 2019) from the BLS reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[305] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 59477). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In this proposed rule, we propose to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy; and (10) update internal cross-references as a result of the redesignations discussed in the proposed rule.

We note that if finalized as proposed, our proposals for the CY 2021 OPPS/ASC proposed rule will not yield a change in burden for the hospitals participating in the Hospital OQR Program as our proposals seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the information collection request that has been approved by OMB 0938–1109 (Expiration date March 31, 2023).[306]

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, and CY 2020 OPPS/ASC final rules with comment period (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; and 84 FR 61469, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270 which expires on December 31, 2022.

2. Summary

In this proposed rule, we propose to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, replace it with the phrase ''data collection period''; (3) move forward all program deadlines falling on a nonwork day consistent with section

[305] Occupational Employment and Wages, May 2019. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.* Accessed March 30, 2020.

[306] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.*

216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period in alignment with the Hospital OQR Program as proposed in section XIV.D.7. that runs concurrent with the existing data submission period and codify this policy. We note that if finalized as proposed, our proposals for the CY 2021 OPPS/ASC proposed rule will not yield a change in burden for the facilities participating in the ASCQR Program as our proposals seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the currently approved information collection request.[307]

D. ICRs for Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. See 84 FR 61142 (November 12, 2019).[308] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with paragraph (b) of 42 CFR 419.83, we propose to add two new service categories to § 419.83(a): Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the two new proposed categories, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, would be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information would generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the proposed July 1, 2021 start date, the first year of the prior authorization for the two new service categories would only include 6 months. Based on CY 2018 data, we estimate that for those first 6 months at a minimum there would be 6,808 initial requests mailed during the year. In addition, we estimate there would be 2,234 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $45,210 (9,042 mailed requests × $5). Based on CY 2018 data for the two new proposed service categories, we estimate that annually at a minimum there would be 13,615 initial requests mailed during a year. In addition, we estimate there would be 4,468 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $90,415 (18,083 mailed requests × $5). We also estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $16.63 with a loaded rate of $33.26. The proposed prior authorization program for these two service categories would not create any new documentation or administrative requirements. Instead, it would just require the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate uses the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the proposed prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total number of submissions for the first year (6 months) would be 30,140 (21,098 submissions through fax or electronic means + 9,042 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the two new service categories, allotted across all providers, would be 24,820 hours (.5 hours × 30,140 submissions plus 3 hours × 3,250 providers for education). The burden cost for the first year (6 months) is $870,723 (24,820 hours × $33.26 plus $45,210 for mailing costs). In addition, we estimate that the total annual number of submissions would be 60,277 (42,194 submissions through fax or electronic means + 18,083 mailed submissions). The annual burden hours for the two new service categories, allotted across all providers, would be 39,889 hours (.5 hours × 60,277 submissions plus 3 hours × 3,250 providers for education). The annual burden cost would be $1,417,107 (39,889 hours × $33.26 plus $90,416 for mailing costs). For the total burden and associated costs for the two new service categories, we estimate the annualized burden to be 34,866 hours and $1,234,979 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938–XXXX will be revised and submitted to OMB for approval.

E. ICRs for the Overall Hospital Quality Star Rating

The Overall Star Rating uses measures that are publicly reported on Hospital Compare or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. We believe the burden associated with measures included in the Overall Star Rating, including requesting withholding of measures from public reporting, is already captured in the respective hospital programs' ICRs and represents no increased information collection burden to hospitals.

F. ICRs for Physician-Owned Hospitals

As discussed in section XIX. of this proposed rule, we propose to modify the physician-owned hospital expansion exception process under the rural provider and hospital ownership

[307] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-016.*

[308] See also Correction Notice issued January 3, 2020 (85 FR 224).

exceptions to the physician self-referral law. Specifically, we proposed to modify the frequency of submission such that a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion to CMS for which CMS has not issued a decision. We do not believe this proposal would result in any changes in burden under the PRA. First, we do not anticipate any changes in the annual number of respondents. Although a high Medicaid facility would be permitted to request an expansion exception more frequently than under current regulations, we believe that removing the cap on the size of an expansion would make more frequent expansion exception requests unlikely. Also, we are not changing the information being collected.

Based on our experience with the expansion exception process to date, we estimate that approximately one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility. We estimate that it takes approximately 6 hours and 45 minutes to prepare an expansion exception request and that a request is prepared by a lawyer. To estimate the cost to prepare a request, we use a 2019 wage rate of $69.86 for lawyers from the Bureau of Labor Statistics,[309] and we double that wage to account for overhead and benefits. The total estimated annual cost is $943.11. We seek comments on these estimates.

Summary of All Burden in This Final Rule

Below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Overall Star Rating[4]	0.0	0.0
Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process	+34,866	+$1.2 million

* Numbers rounded.

[1] Burden changes for the Hospital IQR Program reflect total changes over a four-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination.

[2] Because the FY 2022 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

[3] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[4] Because the Overall Star Rating uses measure data already collected and reported by other programs, the burden is captured in the respective programs and represents no increased burden.

If you comment on these information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by October 13, 2020.

XXII. Waiver of the 60-Day Delayed Effective Date for the Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the OPPS as required by law and are working diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

Due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, the work needed on the OPPS payment rule will not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date of at least 60 days before the start of the fiscal year to which it applies. Up to an additional 30 days may be needed to complete the

[309] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm.*

work needed on this payment rule. The OPPS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the fiscal year to which they are intended to apply. Therefore, due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, we are hereby waiving the 60-day delay in the effective date of the OPPS final rule; it would be contrary to the public interest for CMS to do otherwise. However, we do expect to provide a 30-day delay in the effective date of the final rule in accord with section 5 U.S.C. 553(d) of the Administrative Procedure Act, which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

XXIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2021. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2019, through and including December 31, 2019, and processed through December 31, 2019, and updated cost report information.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2021, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2021. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact for Provisions of This Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2021.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this proposed rule. We are soliciting public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this proposed rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2021, compared to CY 2020, due only to the changes to the OPPS in this proposed rule, would be approximately $1.61 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2021, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2021 would be approximately $83.9 billion, which is approximately $7.5 billion higher than estimated OPPS expenditures in CY 2020. Because the provisions of the OPPS are part of a proposed rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 55 of this proposed rule displays the distributional impact of the CY 2021 changes in OPPS payment to various groups of hospitals and for CMHCs.

Under our CY 2021 policy, drugs and biologicals that are acquired under the 340B Program are proposed to be paid at ASP minus 28.7 percent, WAC minus 28.7 percent, or WAC minus 31.7 percent based on our policy described in V.B.2.b., or 63.90 percent of AWP, as applicable. We note that in the impact table as displayed in this impact analysis, we have modeled current and prospective payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid in CY 2021 under the OPPS at ASP minus 28.7 percent. We also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021.

We estimate that the proposed update to the conversion factor, the CY 2021

frontier wage index adjustment, and other adjustments (not including the effects of outlier payments, the pass-through payment estimates) would increase total OPPS payments by 2.8 percent in CY 2021. The proposed changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, the proposed changes to separately payable drugs acquired under the 340B program, and the payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2020 and CY 2021, considering all proposed budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 2.5 percent.

We estimate the total increase (from changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2021 compared to CY 2020, to be approximately $130 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Tables 56 and 57 of this proposed rule display the redistributive impact of the CY 2021 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2021 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2021 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1736–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 57. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of Proposal To Update the 340B Program Payment Policy

In section X.C. of this proposed rule with comment period, we discuss our proposal to update the payment percentage for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We propose that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from this payment policy in CY 2021. Specifically, in this proposed rule for CY 2021, for hospitals paid under the OPPS (other than those that are excepted for CY 2021), we propose to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 28.7 percent. The difference in total OPPS Part B drug payment for 340B Program drugs at ASP minus 28.7 percent, relative to our current policy of paying ASP minus 22.5 percent, is a decrease of $427 million, which we propose to redistribute through a budget neutral adjustment to the OPPS conversion factor. We also propose in the alternative that the agency could continue the current Medicare payment policy for CY 2021, in which case the 340B policy would not require a change to the budget neutrality adjustment.

To develop an estimated impact of this proposal, we began with CY 2019 outpatient claims data used in ratesetting for the CY 2021 OPPS. We then flagged all claim lines that contained modifier ''JG'' because the presence of this modifier indicates that such claims were subject to the payment adjustment for separately payable non-pass through drugs acquired through the 340B Program in the claims year. We also flagged pass-through drug claim lines with modifier ''TB'' for drugs with pass-through status that will expire by CY 2021. We further subset this population by separating all providers that would be excepted from the policy and then identifying the payment differential between payment at ASP minus 22.5 percent and payment at ASP minus 28.7 percent, which results in a $427 million redistribution, or 0.85 percent increase, to the OPPS conversion factor. This estimate does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. We note that the estimated effect of the proposed policy could change in this final rule with comment period based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

c. Estimated Effects of OPPS Changes on Hospitals

Table 55 shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 55, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2021, we propose to continue to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial

Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2021 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for FY 2021 (which is also the MFP adjustment for FY 2021 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 32739)), resulting in the OPD fee schedule increase factor of 2.6 percent. We are using the OPD fee schedule increase factor of 2.6 percent in the calculation of the CY 2021 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2020 estimates in Table 55 of this proposed rule.

To illustrate the impact of the CY 2021 changes, our analysis begins with a baseline simulation model that uses the CY 2020 relative payment weights, the FY 2020 final IPPS wage indexes that include reclassifications, and the final CY 2020 conversion factor. Table 55 shows the estimated redistribution of the increase or decrease in payments for CY 2021 over CY 2020 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2020 and CY 2021 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.6 percent OPD fee schedule increase factor update to the conversion factor (Column 5); the estimated impact taking into account all payments for CY 2021 relative to all payments for CY 2020, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2021. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2021 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2020 and CY 2021 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2021 will increase Medicare OPPS payments by an estimated 2.5 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.6 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 55 shows the total number of facilities (3,628), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims data to model CY 2020 and CY 2021 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2020 or CY 2021 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,523), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 38 CMHCs at the bottom of the impact table (Table 55) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from a decrease of 0.3 percent to an increase of 0.3 depending on the number of beds. Rural hospitals will increase 0.1 percent overall. Major teaching hospitals will see an expected decrease of 0.4 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2021 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2020 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2021 proposed changes in wage index policy discussed in section II.C. of this CY 2021 OPPS/ASC proposed rule.

We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2021, as described in section II.E. of this proposed rule. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2021 is 0.89, the same as the ratio that was reported for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61191). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we propose to apply in section II.F. of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2021 scaled weights and a CY 2020 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2020 and CY 2021.

Column 4: Effect of the Reduced Payment for 340B Drugs

Column 4 demonstrates the total payment effect of the proposed reduction in payment for drugs purchased under the 340B Program from ASP minus 22.5 percent to ASP minus 28.7 percent. This column includes both the reduced payment for 340B-acquired drugs and the increase to the conversion factor for budget neutrality purposes, which would increase payment for all non-drug items and services. For rural sole community hospitals, this column shows a 0.7 percent increase, reflecting a 0.0 percent decrease for drugs (because we propose that these providers would continue to be exempt from these reductions) and a 0.85 percent increase for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.6 percent. Overall, these changes will increase payments to urban hospitals by 2.8 percent and to rural hospitals by 3.6 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 4.0 percent increase and other rural hospitals receiving an increase of 2.9 percent.

Column 6: All Proposed Changes for CY 2021

Column 6 depicts the full impact of the proposed CY 2021 policies on each hospital group by including the effect of all changes for CY 2021 and comparing them to all estimated payments in CY 2020. Column 6 shows the combined budget neutral effects of Columns 2 through 4; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV. of this proposed rule); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2020 update (and assumed, for modeling purposes, to be the same number for CY 2021), we included 21 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2021 will increase payments to all facilities by 2.5 percent for CY 2021. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2020 and the proposed relative payment weights for CY 2021. We used the final conversion factor for CY 2020 of $80.793 and the proposed CY 2021 conversion factor of $83.697 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629) of 6.3 percent (1.06353) to increase individual costs on the CY 2019 claims, and we used the most recent overall CCR in the April 2020 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2020. Using the CY 2019 claims and a 6.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2020, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,075, will be approximately 1.01 percent of total payments. The estimated current outlier payments of 1.01 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 13.1 percent (1.131096) and the CCRs in the April 2020 OPSF, with an adjustment of 0.97527, to reflect relative changes in cost and charge inflation between CY 2019 and CY 2021, to model the final CY 2020 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629).

Overall, we estimate that facilities will experience an increase of 2.5 percent under this proposed rule in CY 2021 relative to total spending in CY 2020. This projected increase (shown in Column 6) of Table 55 reflects the 2.6 percent OPD fee schedule increase factor, minus 0.05 percent for the change in the pass-through payment estimate between CY 2020 and CY 2021, minus the difference in estimated outlier payments between CY 2020 (1.01 percent) and CY 2021 (1.00 percent). We estimate that the combined effect of all proposed changes for CY 2021 will increase payments to urban hospitals by 2.5 percent. Overall, we estimate that rural hospitals will experience a 3.2 percent increase as a result of the combined effects of all the proposed changes for CY 2021.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.4 percent for major teaching hospitals and an increase of 3.2 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 2.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.4 percent, proprietary hospitals will experience an increase of 4.1 percent, and governmental hospitals will experience an increase of 2.2 percent.

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TABLE 55: ESTIMATED IMPACT OF THE PROPOSED CY 2021 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	All Changes
ALL PROVIDERS *	3,628	0.0	0.2	0.0	2.8	2.5
ALL HOSPITALS	3,523	0.1	0.2	0.0	2.9	2.6
(excludes hospitals held harmless and CMHCs)						
URBAN HOSPITALS	2,772	0.0	0.2	-0.1	2.8	2.5
LARGE URBAN	1,431	0.1	0.2	-0.1	2.8	2.5
(GT 1 MILL.)						
OTHER URBAN	1,341	0.0	0.2	-0.1	2.8	2.4
(LE 1 MILL.)						
RURAL HOSPITALS	751	0.1	0.4	0.4	3.6	3.2
SOLE COMMUNITY	368	0.1	0.5	0.7	4.0	3.5
OTHER RURAL	383	0.1	0.2	0.0	2.9	2.7
BEDS (URBAN)						
0 - 99 BEDS	927	0.3	0.3	0.5	3.7	3.4
100-199 BEDS	789	0.3	0.2	0.3	3.4	3.1
200-299 BEDS	449	0.2	0.2	0.1	3.2	2.9
300-499 BEDS	383	0.1	0.3	0.0	2.9	2.6
500 + BEDS	224	-0.3	0.0	-0.6	1.7	1.6
BEDS (RURAL)						
0 - 49 BEDS	324	0.3	0.5	0.5	3.9	3.5
50- 100 BEDS	262	0.3	0.5	0.5	3.9	3.4
101- 149 BEDS	88	0.0	0.3	0.3	3.2	2.8
150- 199 BEDS	38	0.0	0.4	0.1	3.1	2.9
200 + BEDS	39	-0.1	0.3	0.3	3.1	3.0
REGION (URBAN)						
NEW ENGLAND	133	-0.1	0.7	-0.2	3.0	2.0
MIDDLE ATLANTIC	325	-0.2	0.0	-0.1	2.3	2.2
SOUTH ATLANTIC	452	0.1	0.1	-0.1	2.7	2.7
EAST NORTH CENT.	436	0.0	-0.1	0.0	2.5	2.4
EAST SOUTH CENT.	162	-0.1	0.0	-0.3	2.2	2.1

WEST NORTH CENT.	183	-0.1	0.7	-0.2	2.9	1.9
WEST SOUTH CENT.	461	0.3	0.2	0.2	3.4	3.3
MOUNTAIN	204	0.2	0.2	-0.1	3.0	2.3
PACIFIC	367	0.2	0.2	-0.1	2.9	2.8
PUERTO RICO	49	0.7	-0.3	0.8	3.7	3.7
REGION (RURAL)						
NEW ENGLAND	20	0.0	-0.1	0.3	2.8	2.7
MIDDLE ATLANTIC	50	0.0	0.3	0.4	3.2	3.2
SOUTH ATLANTIC	114	0.1	0.0	0.2	2.9	2.8
EAST NORTH CENT.	120	0.1	0.7	0.5	4.0	3.8
EAST SOUTH CENT.	146	0.2	0.0	0.0	2.9	2.8
WEST NORTH CENT.	91	0.0	1.0	0.6	4.3	3.1
WEST SOUTH CENT.	139	0.3	0.1	0.6	3.7	3.6
MOUNTAIN	48	0.0	2.0	0.6	5.2	3.1
PACIFIC	23	0.2	-0.3	0.3	2.8	2.7
TEACHING STATUS						
NON-TEACHING	2,367	0.3	0.2	0.3	3.5	3.2
MINOR	779	0.2	0.4	0.1	3.2	2.8
MAJOR	377	-0.4	0.0	-0.6	1.6	1.4
DSH PATIENT PERCENT						
0	11	0.5	-0.1	0.8	3.8	3.7
GT 0 - 0.10	268	0.5	0.2	0.8	4.1	3.8
0.10 - 0.16	241	0.3	0.0	0.7	3.7	3.4
0.16 - 0.23	591	0.4	0.2	0.7	4.0	3.7
0.23 - 0.35	1,081	0.0	0.3	-0.1	2.7	2.4
GE 0.35	906	-0.2	0.2	-0.6	2.0	1.8
DSH NOT AVAILABLE **	425	-1.0	0.2	0.7	2.5	2.3
URBAN TEACHING/DSH						
TEACHING & DSH	1,041	-0.1	0.2	-0.3	2.4	2.1
NO TEACHING/DSH	1,313	0.4	0.1	0.3	3.4	3.2
NO TEACHING/NO DSH	11	0.5	-0.1	0.8	3.8	3.7
DSH NOT AVAILABLE2	407	-0.9	0.2	0.7	2.6	2.4
TYPE OF OWNERSHIP						
VOLUNTARY	1,971	0.0	0.2	-0.1	2.7	2.4
PROPRIETARY	1,099	0.7	0.3	0.8	4.4	4.1
GOVERNMENT	453	-0.1	0.1	-0.3	-0.3	2.2
CMHCs	38	-2.0	0.1	0.9	1.5	1.3

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2021 OPPS policies and compares those to the CY 2020 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The proposed rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because in CY 2021 the proposed target payment-to-cost ratio is the same as that of CY 2020 (0.90 and reduced to 0.89 in accordance with the 21st Century Cures Act)
Column (4) shows the impact of the proposed CY 2021 OPPS changes to 340B drug payment and the corresponding budget neutrality adjustment.
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).
Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.
These 3,628 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 55 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2020, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims used for ratesetting in the proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 1.3 percent increase in payments from CY 2020 (shown in Column 6). We note that this includes the trimming methodology as well as the proposed CY 2021 floor on geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this proposed rule. The CY 2021 proposal to establish a floor based on geometric mean costs, rather than based on a predetermined payment rate, makes the OPPS budget neutrality adjustments for both the weight scalar and the conversion factor applicable.

Column 3 shows that the estimated impact of adopting the proposed FY 2021 wage index values will result in an increase of 0.1 percent to CMHCs. Column 5 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2021 and the proposed FY 2021 wage index updates, will result in an estimated increase of 1.5 percent. Column 6 shows that adding the proposed changes in outlier and pass-through payments will result in a total 1.3 percent increase in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2021.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this CY 2021 OPPS/ASC proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.1 percent for all services paid under the OPPS in CY 2020. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2020 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the final changes in the final rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.61 billion in program payments for OPPS services furnished in CY 2021. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the proposed changes in the proposed rule would increase these Medicaid beneficiary payments by approximately $115 million in CY 2021. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking thirty percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $115 million Medicaid increase, approximately $65 million will be from the Federal Government and $50 million would be from State government.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

- Alternatives Considered for the Payment Adjustment for Separately Paid Drugs Acquired through the 340B Program

We refer readers to section V.B.6. of this CY 2021 OPPS/ASC proposed rule for a discussion of our proposed policy to apply a payment adjustment of ASP minus 28.7 percent for separately paid non-pass through drugs acquired the 340B Program. We also propose in the

alternative to maintain the same payment adjustment percentage of ASP minus 22.5 percent as initially established under the CY 2018 OPPS policy (82 FR 59350 through 59369). We note that effects of the proposal and its corresponding budget neutrality adjustment compared to the alternative considered are provided in Column 4 of table 55.

2. Estimated Effects of CY 2021 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2021 ASC relative payment weights by scaling the proposed CY 2021 OPPS relative payment weights by the proposed ASC scalar of 0.8494. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 56 and 57 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, we propose that the CY 2021 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which we propose would be the hospital market basket for CY 2021. We calculated the CY 2021 ASC conversion factor by adjusting the CY 2020 ASC conversion factor by 0.9999 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2020 and CY 2021 and by applying the CY 2021 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus an MFP adjustment of 0.4 percentage point). The proposed CY 2021 ASC conversion factor is $48.984 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2021 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2021 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2021 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2021 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2021 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 57 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2020 payments to estimated proposed CY 2021 payments, and Table 56 shows a comparison of estimated CY 2020 payments to estimated proposed CY 2021 payments for procedures that we estimate will receive the most Medicare payment in CY 2020.

In Table 57, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 57.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2020 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2020 ASC payments.
- Column 3—Estimated CY 2021 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2021 compared to CY 2020.

As shown in Table 56, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2021 will result in a 3-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for nervous system procedures, 4-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 3-percent increase in aggregate payment amounts for cardiovascular system procedures, and a 5-percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.6 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of

services can be higher or lower than a 2.6-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 4-percent increase in proposed aggregate gastrointestinal procedure payments due to an increase in hospital reported costs for Level 1 and Level 2 upper and lower gastrointestinal payment categories under the OPPS. The increases in payment weights for gastrointestinal procedure payments is further increased by the proposed 2.6 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 57 provided later in this section.

TABLE 56: ESTIMATED IMPACT OF THE PROPOSED CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2021 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP [310]

Surgical Specialty Group (1)	Estimated CY 2020 ASC Payments (in Millions) (2)	Estimated CY 2021 Percent Change (3)
Total	$5,446	3
Eye and ocular adnexa	$1,811	3
Nervous system	$1,178	3
Digestive system	$908	4
Musculoskeletal system	$693	4
Cardiovascular system	$270	3
Genitourinary system	$201	5

Table 57 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2021. The table displays 30 of the procedures receiving the greatest estimated CY 2020 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2020 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2020 ASC payment rates. The estimated CY 2020 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2021 Percent Change reflects the percent differences between the estimated ASC payment for CY 2020 and the estimated payment for CY 2021 based on the proposed update.

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[310] Projected impacts are the same under all proposals for the ASC Covered Procedures List, given the lack of prior ASC utilization data for the procedures being added.

TABLE 57: ESTIMATED IMPACT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2020 ASC Payment (in millions) (3)	Estimated CY 2021 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,259	3
63685	Insrt/redo spine n generator	$295	4
45380	Colonoscopy and biopsy	$247	3
63650	Implant neuroelectrodes	$189	2
43239	Egd biopsy single/multiple	$185	3
45385	Colonoscopy w/lesion removal	$184	3
0191T	Insert ant segment drain int	$125	4
64483	Njx aa&/strd tfrm epi l/s 1	$120	1
66982	Xcapsl ctrc rmvl cplx wo ecp	$92	3
64635	Destroy lumb/sac facet jnt	$86	1
64493	Inj paravert f jnt l/s 1 lev	$78	1
36902	Intro cath dialysis circuit	$78	1
29827	Arthroscop rotator cuff repr	$76	4
66821	After cataract laser surgery	$67	-1
64590	Insrt/redo pn/gastr stimul	$63	6
C9740	Cysto impl 4 or more	$58	4
22869	Insj stablj dev w/o dcmprn	$55	6
62323	Njx interlaminar lmbr/sac	$55	1
G0105	Colorectal scrn; hi risk ind	$53	4
15823	Revision of upper eyelid	$40	5
G0121	Colon ca scrn not hi rsk ind	$39	4
45378	Diagnostic colonoscopy	$39	4
64721	Carpal tunnel surgery	$37	1
63655	Implant neuroelectrodes	$33	8
65820	Relieve inner eye pressure	$29	1
62362	Implant spine infusion pump	$28	4
64561	Implant neuroelectrodes	$28	0
67042	Vit for macular hole	$28	1
29881	Knee arthroscopy/surgery	$28	4
64490	Inj paravert f jnt c/t 1 lev	$27	1

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c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2021 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures we propose to add to the ASC list of covered surgical procedures and for those we propose to designate as office-based for CY 2021. For example, using 2019 utilization data and proposed CY 2021 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments will be reduced by approximately $6 million in CY 2021 and total beneficiary copayments will decline by approximately $1.2 million in CY 2021. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital

inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we propose to designate as office-based in CY 2021, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 58, illustrates the classification of expenditures for the CY 2021 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2021 OPD fee schedule increase. The second accounting statement, Table 59, illustrates the classification of expenditures associated with the 2.6 percent CY 2021 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The estimated costs of ICR Burden and Regulatory Familiarization are included in Table 60.

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TABLE 58: ACCOUNTING STATEMENT: CY 2021 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2020 TO CY 2021 ASSOCIATED WITH THE FINAL CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,610 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,610 million

TABLE 59: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2020 TO CY 2021 AS A RESULT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$110 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$110 million

TABLE 60: ESTIMATED COSTS IN CY 2021

CATEGORY	Costs
ICR Burden	$1.58 million*
Regulatory Familiarization	$3.37 million**

*The annual estimates are in 2018 year dollars which includes the impact of hospital outpatient QRP and prior authorization process and requirements for certain OPD services.

** Regulatory familiarization costs occur upfront only.

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4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the 3,144 hospitals that met eligibility requirements for the CY 2020 payment determination, we determined that 78 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. We do not propose to add any quality measures to the Hospital OQR Program measure set for the CY 2022 or CY 2023 payment determinations.

b. Impact of CY 2021 Proposals

We do not anticipate that any of the CY 2021 Hospital OQR program proposals will impact the number of facilities that will receive payment reductions. In this proposed rule, we propose to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j) ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (proposed redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy''; and (10) update internal cross-references as a result of the redesignations discussed in the proposed rule.''

We do not anticipate that the proposals affecting the Hospital OQR program in this proposed rule will impact the number of hospitals that will receive payment reductions.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV.B. of this proposed rule, we discuss our finalized policies affecting the ASCQR Program. For the CY 2020 payment determination, of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 195 ASCs did not meet the requirements to receive the full annual payment update. We do not propose to add or remove any quality measures to the ASCQR Program measure set for future calendar year payment determinations.

b. Impact of CY 2021 Proposals

In sections XV.C. and XV.D. of this proposed rule, we propose to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, replace it with the phrase ''data collection period,'' and use the phrase ''data collection period'' wherever the phrase ''data collection time period'' is found in the preamble of this proposed rule; (3) move forward all program deadlines falling on a nonwork day consistent with the section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period similar to that in the Hospital OQR Program in section XIV.D.7. that runs concurrent with the existing data submission period from January 1 through May 15 and codify this policy.

We do not anticipate that the proposals affecting the ASCQR program in this proposed rule will impact the number of ASCs that will receive payment reductions.

6. Effects of Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[311] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also propose to add those service categories to § 419.83(a). We propose that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. The proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector of this proposal to require prior authorization for two additional service categories is dependent on the number of claims affected. Table 61, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the two new service categories combined. The values populating this table were obtained from the cost reflected in Table 62, Annual Private Sector Costs, and Table 63, Estimated Annual Administrative Costs to CMS. Together, Tables 62 and 63 combine to convey the overall economic impact to the health sector for the two new service categories, which is illustrated in Table 61. It should be noted that due to the proposed July start date for prior authorization for these two new service categories, year one would include only 6 months of prior authorization requests.

Based on the estimate, the overall economic cost impact of this proposal is approximately $2.9 million in the first year based on 6 months for the two new

[311] See also Correction Notice issued January 3, 2020 (85 FR 224).

service categories. The 5-year impact is approximately $22.9 million, and the 10-year impact is approximately $47.9 million. The 5- and 10-year impacts account for year one including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $31,844,388. We believe there are likely to be other benefits that result from the proposed prior authorization requirement for the two new service categories, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We are soliciting public comments on the potential increased costs and benefits associated with this proposed provision for the two new service categories.

TABLE 61: OVERALL ECONOMIC COST IMPACT TO THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$870,723	$6,539,151	$13,624,686
Administrative Costs to CMS	$2,017,317	$16,349,353	$34,264,398
Total Economic Impact to Health Sector	$2,888,040	$22,888,504	$47,889,084

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this proposal are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant; if finalized, the proposal will change the billing practices of those providers. We believe that the purpose of the statute and this proposal is to avoid unnecessary utilization of OPD services. Therefore, we do not view decreased revenues from the two additional OPD services categories subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect will be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. This proposal will offer an additional protection to a provider's cash flow as the provider will know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

(1) Private Sector Costs

We do not believe that this proposal will significantly affect the number of legitimate claims submitted for these new service categories. However, we do expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the two proposed additional service categories is equivalent to that of submitting documentation and clerical activities associated for prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

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TABLE 62: Year 1 (6 Month) Private Sector Costs

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	15,884	0.5	7,942	$264,158
Fax and Electronic Submitted Requests-Resubmissions	5,214	0.5	2,607	$86,702
Mailed in Requests-Initial Submissions	6,808	0.5	3,404	$113,210
Mailed in Requests-Resubmissions	2,234	0.5	1,117	$37,158
Mailing Costs	9,042	$5	NA	$45,210
Provider Demonstration-Education	3,250	3	9,750	$324,285
Total			24,820	$870,723

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(2) Administrative Costs to CMS

CMS will incur additional costs associated with processing the proposed prior authorization requests for the two new service categories. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 63: Year 1 (6 Month) Estimated Administrative Costs to CMS

Cervical Fusion with Disc Removal	Implanted Spinal Neurostimulators	Combined
$489,916	$1,077,401	$2,017,317

(3) Estimated Beneficiary Costs

We expect a reduction in the utilization of the two new Medicare OPD service categories when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although the proposal is designed to permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There will be quantifiable benefits for this proposal because we expect a reduction in the unnecessary utilization of those two new Medicare OPD service categories subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on other prior authorization programs, we estimate our savings based on a 50 percent reduction in improper payments, using a 10 percent improper payment rate. We estimate that for the first six months, there would be savings of $15,922,194 overall. Annually, we estimate an overall gross savings of $31,844,388. This savings represents a Medicare benefit from a more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also

include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the two proposed additional OPD services categories would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine his or her condition and what services are needed and medically necessary. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and the documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced by the requirement that a provider submit clinical documentation created as part of its prior authorization request.

7. Effects of Proposed Revision to the Laboratory Date of Service Policy

In section XVIII. of this proposed rule, we discuss our proposal to add cancer-related protein-based MAAAs to the laboratory date of service (DOS) provisions at § 414.510(b)(5). We also propose to exclude these tests from the OPPS packaging policy, which is discussed in section II.a.3 of this proposed rule. These proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5). While there may be some impact under the hospital OPPS resulting from additional testing being excluded from OPPS packaging policy and paid at the CLFS rate instead of the OPPS bundled rate, we expect this change to be budget neutral for scoring purposes. Accordingly, the discussion in sections II.a.3. and XVIII. of this proposed rule is not reflected in Table 55 in the regulatory impact analysis under section XXIV of this proposed rule.

8. Effects of Requirements for the Overall Hospital Quality Star Ratings

In section E. Current and Proposed Overall Star Rating Methodology of the preamble of this proposed rule, we discuss our proposal as it relates to the Overall Star Rating methodology. The Overall Star Rating uses measures that are publicly reported on *Hospital Compare* or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Star Rating, including forms used to request withholding of publicly reported measure data and the Overall Star Rating (for CAHs), is already captured in the respective hospital programs' burden estimates and represents no increased information collection burden to hospitals.

In this proposed rule, however, we propose that hospitals have the opportunity to review confidential reports containing their measure, measure group, and Overall Star Rating results for at least 30 days prior to publication of the Overall Star Rating. We believe that reviewing the Overall Star Rating in confidential reports prior to public reporting represents additional burden to hospitals.

In this CY 2021 OPPS/ASC proposed rule, we are using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $19.40 [312] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We estimate that the non-information collection burden associated with all non-VHA hospitals reviewing their Overall Star Rating preview report prior to public reporting to be 2 hours per hospital, which includes time to review the report and ask any questions about the calculation necessary to increase comprehension. Estimating that 4,500 hospitals that will receive an Overall Star Rating hospital specific report (HSR), regardless if they meet the reporting thresholds to be assigned a star rating, we estimate the overall non-information collection burden to be $397,710 annually [$38.80 × 2 hours per preview report × once per year × 4,500 hospitals]. For CAHs specifically, which are included in the estimate above, we estimate that half of CAHs will be eligible for an Overall Star Rating (using an estimate of 1,300 total CAHs in the United States), which represents a burden of $100,890 annually [650 CAHs × 2 hours per preview report × once per year × $38.80].

To simulate the impact of the combined methodology updates, we used January 2020 Overall Star Rating publication data (using October 2019 publicly reported measure data on *Hospital Compare)* to conduct analyses that describe the overall distribution of star ratings, reclassification of star ratings, and distribution of star ratings across different types of hospitals. We conducted these analyses following three proposals (referred to as combined methodology proposals): (1) Grouping measures into five, rather than seven, measure groups; (2) using a simple average of measure scores to calculate measure group scores; and (3) updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group to receive a star rating. We also conducted these analyses separately with the combined methodology proposals and the additional proposal of peer grouping hospitals by number of measure groups for which the hospital reports at least three measures, with the combined methodology proposal and the additional proposal of Readmission measure group stratification by dual-eligible peer groups, and with the combined methodology proposals and the additional proposals of both peer grouping by number of measure groups and Readmission measure group stratification by dual-eligible peer groups to specifically solicit further comment on these proposals. Please note that the ultimate star ratings distribution and reclassification with the proposed methodology updates in CY 2021 will differ depending on measure additions and removals from CMS quality programs, and therefore public reporting, and changes in hospital measure performance.

The combined methodology proposals of (1) grouping measures into five measure groups, (2) using a simple average of measure scores to calculate measure group scores, and (3) updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in

[312] Bureau of Labor Statistics. (2019, September 4). *Occupational Outlook Handbook: Medical Records and Health Information Technicians.* Retrieved from *www.bls.gov*: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

each group to receive a star rating, would result in a similar percent of hospitals that would and would not receive a star rating, regardless of peer grouping by number of measure groups or Readmission measure group stratification by dual-eligibility groups. However, slightly fewer safety-net and critical access hospitals (CAHs), would receive a star rating with the new methodology due to the proposal to update the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group. Specifically, approximately 30 percent of specialty, 90 percent of teaching, 60 percent of safety-net, and 40 percent of CAHs meet the proposed reporting thresholds of three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group.

The combined methodology proposals of grouping measures into five, rather than seven, measure groups, using a simple average of measure scores to calculate measure group scores, and updating the reporting thresholds to require at least three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each group to receive a star rating results in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics:

- With the combined methodology proposals, there would be a similar distribution of star ratings with more three (23 percent) and four (23 percent) star ratings and fewer one (4 percent), two (13 percent), and five (13 percent) star ratings (Table 64).
- Given the substantial change in the proposed methods, particularly using a simple average of measure scores to calculate measure groups scores, we would expect there to be considerable changes in hospital star ratings from the current methodology to the proposed methodology. With the combined proposed methodology, 1,796 (53 percent) hospitals would receive the same star rating, 1,468 (43 percent) hospitals would shift up or down one star, 135 (4 percent) hospitals would shift up or down two stars, 9 (0.3 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospital would shift up or down four stars (Table 65).
- With the combined methodology proposals, most hospital characteristics have a similar distribution of star ratings to that of all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 72.
  - More specialty hospitals with three (4 percent), four (7 percent), and five (19 percent) stars than one (0 percent) or two (0 percent) stars.
  - More DSH hospitals with one (6 percent), two (19 percent), and three (31 percent) stars and fewer DSH hospitals with five stars (11 percent). Also, there would be more DSH hospitals with one (3 percent for DSH quintiles 1 and 2 to 17 percent for DSH quintile 5) and two stars (14 percent for DSH quintile 1 to 25 percent for DSH quintile 5) and fewer DSH hospitals with four (36 percent for DSH quintile 1 to 16 percent for DSH quintile 5) and five (18 percent for DSH quintile 1 to 5 percent for DSH quintile 5) stars with increasing DSH quintile.
  - More CAHs with five (13 percent) and four (14 percent) stars than one (1 percent), two (3 percent), and three (8 percent) stars.
  - More hospitals with one (2 percent for hospitals with 1–99 beds to 9 percent for hospitals with 400 or more beds) and two stars (9 percent for hospitals with 1–99 beds to 26 percent for hospitals with 300–399 beds and 24 percent for hospitals with 400 or more beds) with increasing bed size.
  - Slightly larger urban hospitals with one (8 percent) and two (19 percent) stars than other urban hospitals with one (4 percent) and two (17 percent) stars or rural hospitals with one (3 percent) and two (15 percent) stars. There would also be slightly fewer large urban hospitals with four (24 percent) stars than other urban hospitals with four (27 percent) stars or rural hospitals with four (30 percent) stars.

The combined methodology proposals with the additional proposal of peer grouping by number of measure groups would result in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics. With the combined methodology proposals and the additional proposal of peer grouping:

- There would be a similar distribution of star ratings with more three (22 percent) and four (23 percent) star ratings and fewer one (4 percent), two (14 percent), and five (12 percent) star ratings (Table 64).
- Approximately 2,676 (78 percent), 1,692 (50 percent) hospitals would receive the same star rating, 1,482 (43 percent) hospitals would shift up or down one star, 184 (5 percent) hospitals would shift up or down two stars, 10 (0.3 percent) hospitals would shift up or down three stars, and one (0.03 percent) hospital would shift up or down four stars (Table 66).
- Most hospital characteristics have a similar distribution of star ratings to that of all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed below (Table 73).
  - More specialty hospitals with three (5 percent), four (7 percent), and five (17 percent) stars than one (0 percent) and two (1 percent) stars.
  - More DSH hospitals with two stars (13 percent for DSH quintile 1 to 25 percent for DSH quintile 5) and fewer DSH hospitals with four (34 percent for DSH quintile 1 to 18 percent for DSH quintile 5) and five (23 percent for DSH quintile 1 to 5 percent for DSH quintile 5) stars with increased DSH quintiles.
  - Slightly larger urban hospitals with one star (8 percent) than other urban hospitals with one star (4 percent) or rural hospitals with one star (3 percent). There would also be slightly fewer large urban hospitals with four stars (24 percent) than other urban hospitals with four stars (29 percent) or rural hospitals with four stars (29 percent).

The combined methodology proposal with the addition of stratifying Readmission measure group scores by dual-eligibility peer groups, using peer group quintiles assigned by the HRRP annually, would result in the below distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristics. With the combined methodology proposals and the additional proposal of Readmission stratification by dual-eligibility groups:

- There is a similar distribution of star ratings with more three (24 percent) and four (24 percent) star ratings and fewer one (3 percent), two (12 percent), and five (13 percent) star ratings (Table 64).
- Approximately 1,715 (50 percent) hospitals would receive the same star rating, 1,523 (45 percent) hospitals would shift up or down one star, 163 (5 percent) hospitals would shift up or down two stars, 7 (0.2 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospitals would shift up or down four stars (Table 67).
- Most hospital characteristics have a similar distribution of star rating to that of the all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 74.
  - More specialty hospitals with four (7 percent) and five (20 percent) stars compared to one (0 percent) or two (1 percent) stars.
  - Similar star rating distribution for safety-net and non-safety-net hospitals,

with more three (18 percent safety-net; 26 percent non-safety-net) and four (18 percent safety-net; 27 percent non-safety-net) stars and fewer one (4 percent safety-net; 2 percent non-safety-net), two (12 percent safety-net; 13 percent non-safety-net), or five (9 percent safety-net; 14 percent non-safety-net) stars.

○ More DSH Quintile 5 hospitals with one (10 percent) and two (24 percent) stars than DSH Quintile 1 hospitals with one (2 percent) and two (13 percent) stars. Also, there would be fewer hospitals with four (37 percent for DSH quintile 1 to 20 percent for DSH quintile 5) and five stars (17 percent for DSH quintile 1 to 7 percent for DSH quintile 5) with increasing DSH quintiles.

○ More CAHs receiving a star rating with four (14 percent) and five (14 percent) stars than one (1 percent) or two (3 percent) stars.

○ More hospitals with one (1 percent for hospitals with 1 to 99 beds to 7 percent for hospitals with 300–399 beds and 5 percent for hospitals with 400 or more beds) and two stars (7 percent for hospitals with 1 to 99 beds to 26 percent for hospitals with 300–399 beds and 23 percent for hospitals with 400 or more beds) with increasing bed size.

In further support of our additional proposals to peer group hospitals by the number of measure groups and stratify the Readmission measure group by dual-eligibility groups, we also conducted analyses examining the distribution of star ratings, reclassification of star ratings, and distribution of star ratings across hospital characteristic analyses on the combined methodology proposals with the additional proposals of peer grouping and Readmission stratification. With the combined methodology proposals and the additional proposals of both peer grouping by number of measure groups and Readmission stratification by dual-eligibility groups:

• There would be a similar distribution of star ratings with more three (24 percent) and four (24 percent) star ratings and fewer one (3 percent), two (12 percent), and five (12 percent) star ratings (Table 64).

• Approximately 1,743 (51 percent) hospitals would receive the same star rating, 1,477 (43 percent) hospitals would shift up or down one star, 180 (5 percent) hospitals would shift up or down two stars, 8 (0.2 percent) hospitals would shift up or down three stars, and 1 (0.03 percent) hospitals would shift up or down four stars (Table 68).

• Most hospital characteristics have a similar distribution of star rating to that of the all hospitals. A few notable differences in the distribution of star ratings across hospital characteristics compared to all hospitals are listed in Table 75.

○ More specialty hospitals with four (10 percent) and five (15 percent) stars compared to one (0 percent) or two (1 percent) stars.

○ More DSH hospitals with one (5 percent), two (17 percent), and three (30 percent) stars and fewer DSH hospitals with five stars (14 percent). Also, there would be more hospitals with one (3 percent for quintile 1 to 11 percent for quintile 5) and two (13 percent for quintile 1 to 24 percent for quintile 5) stars and fewer hospitals five stars (21 percent for quintile 1 to 7 percent for quintile 5) with increasing DSH quintiles.

○ More CAHs with four (15 percent) and five (6 percent) stars than one (1 percent) or two (5 percent) stars.

○ More hospitals with one (1 percent for hospitals with 1 to 99 beds to 8 percent for hospitals with 300 to 399 beds and 6 percent for hospitals with 400 or more beds) and two stars with increasing bed size.

To isolate the effects of our additional proposals to peer group hospitals by the number of measure groups and stratify the Readmission measure group by dual-eligibility groups, we also conducted reclassification analyses comparing the two additional proposals.

• When comparing the combined methodology proposals with the additional proposals of peer grouping by the number of measure groups and stratifying the Readmission measure group by dual-eligibility peer groups to the combined methodology proposals with the additional proposal to stratify the Readmission measure group by dual-eligibility peer groups but without the proposal to peer group by number of measure groups, 2,676 (78 percent) hospitals would receive the same star rating, and 764 (22 percent) hospitals would shift up or down one star. No hospitals would move more than one star (Table 69).

• When comparing the combined methodology proposals with the additional proposals to peer group hospitals by the number of measure groups and stratifying the Readmission measure group by dual-eligibility peer groups to the combined methodology proposals with our proposal to peer group by the number of measure groups but without the proposal to stratify the Readmission measure group by dual-eligibility peer groups, 3,093 (90 percent) hospitals would receive the same star rating, and 347 (10 percent) hospitals would shift up or down one star. No hospitals would move more than one star (Table 70).

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TABLE 64: OVERALL STAR RATING DISTRIBUTION BY CURRENT METHODOLOGY, COMBINED METHODOLOGY PROPOSALS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING, COMBINED METHODOLOGY PROPOSALS WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS, AND COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING AND READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating	Current Methodology	Combined Methodology Proposals	Combined Methodology Proposals, Peer Grouping	Combined Methodology Proposals, Readmission Stratification	Combined Methodology Proposals, Peer Grouping, Readmission Stratification
1	228 (4.97%)	197 (4.30%)	184 (4.01%)	122 (2.66%)	145 (3.16%)
2	710 (15.48%)	597 (13.02%)	620 (13.52%)	555 (12.10%)	567 (12.36%)
3	1,119 (24.4%)	1,037 (22.61%)	1,026 (22.37%)	1,078 (23.51%)	1,087 (23.70%)
4	1,136 (24.77%)	1,033 (22.53%)	1,051 (22.92%)	1,101 (24.01%)	1,093 (23.83%)
5	407 (8.87%)	576 (12.56%)	559 (12.19%)	584 (12.73%)	548 (11.95%)
N/A	986 (21.5%)	1,146 (24.99%)	1,146 (24.99%)	1,146 (24.99%)	1,146 (24.99%)

TABLE 65: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, No Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	113	96	17	0	0	226
	50.0%	42.5%	7.5%	0%	0%	
2	65	345	253	38	2	703
	9.3%	49.1%	36.0%	5.4%	0.3%	
3	8	130	528	340	40	1,046
	0.8%	12.4%	50.5%	32.5%	3.8%	
4	5	19	218	543	256	1,041
	0.5%	1.8%	20.9%	52.2%	24.6%	
5	1	2	13	110	267	393
	0.3%	0.5%	3.3%	28.0%	67.9%	
Total	192	592	1,029	1,031	565	3,409

TABLE 66: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING AND WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	107	94	25	0	0	226
	47.4%	41.6%	11.1%	0%	0%	
2	58	318	265	60	2	703
	8.3%	45.2%	37.7%	8.5%	0.3%	
3	7	163	488	345	43	1,046
	0.7%	15.6%	46.7%	33.0%	4.1%	
4	7	37	228	541	228	1,041
	0.7%	3.6%	21.9%	52.0%	21.9%	
5	1	1	12	101	278	393
	0.3%	0.3%	3.1%	25.7%	70.7%	
Total	180	613	1,018	1,047	551	3,409

TABLE 67: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, No Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	76	126	24	0	0	226
	33.6%	55.6%	10.6%	0%	0%	
2	34	306	305	56	2	703
	4.8%	43.5%	43.4%	8.0%	0.3%	
3	3	100	522	370	51	1,046
	0.3%	9.6%	50.0%	35.4%	4.9%	
4	4	17	207	552	261	1,041
	0.4%	1.6%	19.9%	53.0%	25.1%	
5	1	1	12	120	259	393
	0.3%	0.3%	3.1%	30.5%	65.9%	
Total	118	550	1,070	1,098	573	3,409

TABLE 68: STAR RATING RECLASSIFICATION, CURRENT METHODOLOGY VS COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Current Methodology)	Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	86	111	29	0	0	226
	38.1%	49.1%	12.8%	0%	0%	
2	42	305	290	65	1	703
	6.0%	43.4%	41.3%	9.3%	0.1%	
3	6	122	518	351	49	1,046
	0.6%	11.7%	49.5%	33.6%	4.7%	
4	6	20	232	563	220	1,041
	0.6%	1.9%	22.3%	54.1%	21.1%	
5	1	1	11	109	271	393
	0.3%	0.3%	2.8%	27.7%	69.0%	
Total	141	559	1,080	1,088	541	3,409

TABLE 69: STAR RATING RECLASSIFICATION, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS VS COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)	Star Rating (Combined Methodology Proposals, No Peer Grouping, Readmission Stratification)					
	1	2	3	4	5	Total
1	120	25	0	0	0	145
	82.8%	17.2%	0%	0%	0%	
2	2	492	73	0	0	567
	0.4%	86.8%	12.9%	0%	0%	
3	0	38	880	169	0	1,087
	0%	3.5%	90.0%	15.6%	0%	
4	0	0	125	784	184	1,093
	0%	0%	11.4%	71.7%	16.8%	
5	0	0	0	148	400	548
	0%	0%	0%	27.0%	73.0%	
Total	122	555	1,078	1,101	584	3,440

TABLE 70: STAR RATING RECLASSIFICATION, COMBINED METHODOLOGY PROPOSALS, PEER GROUPING, READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS VS COMBINED METHODOLOGY PROPOSALS, PEER GROUPING WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Star Rating (Combined Methodology Proposals, Peer Grouping, Readmission Stratification)	Star Rating (Combined Methodology Proposals, Peer Grouping, No Readmission Stratification)					
	1	2	3	4	5	Total
1	145	0	0	0	0	145
	100%	0%	0%	0%	0%	
2	39	517	11	0	0	567
	6.9%	91.2%	1.9%	0%	0%	
3	0	103	934	50	0	1,087
	0%	9.5%	85.9%	4.6%	0%	
4	0	0	81	975	37	1,093
	0%	0%	7.4%	89.2%	3.4%	
5	0	0	0	26	522	548
	0%	0%	0%	4.7%	95.3%	
Total	184	620	1,026	1,051	559	3,440

TABLE 71: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, CURRENT METHODOLOGY

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	228 (4.97%)	710 (15.48%)	1119 (24.40%)	1136 (24.77%)	407 (8.87%)	986 (21.50%)
Specialty	0 (0%)	0 (0%)	3 (2.48%)	9 (7.44%)	21 (17.36%)	88 (72.73%)
Non-Specialty	228 (5.24%)	705 (16.20%)	1102 (25.33%)	1100 (25.28%)	380 (8.73%)	836 (19.21%)
N/A	0 (0%)	5 (4.39%)	14 (12.28%)	27 (23.68%)	6 (5.26%)	62 (54.39%)
Major Teaching	45 (18.67%)	55 (22.82%)	67 (27.80%)	50 (20.75%)	23 (9.54%)	1 (0.41%)
Minor Teaching	112 (7.80%)	307 (21.39%)	375 (26.13%)	358 (24.95%)	181 (12.61%)	102 (7.11%)
Non-Teaching	71 (2.54%)	343 (12.27%)	663 (23.71%)	701 (25.07%)	197 (7.05%)	821 (29.36%)
N/A	0 (0%)	5 (4.39%)	14 (12.28%)	27 (23.68%)	6 (5.26%)	62 (54.39%)
Safety-Net	76 (5.74%)	170 (12.83%)	310 (23.40%)	276 (20.83%)	63 (4.75%)	430 (32.45%)
Non-Safety-Net	150 (4.81%)	529 (16.98%)	783 (25.13%)	826 (26.51%)	337 (10.82%)	491 (15.76%)
N/A	2 (1.38%)	11 (7.59%)	26 (17.93%)	34 (23.45%)	7 (4.83%)	65 (44.83%)
Non-DSH	8 (1.64%)	31 (6.34%)	91 (18.61%)	126 (25.77%)	90 (18.40%)	143 (29.24%)
DSH	219 (7.98%)	641 (23.36%)	802 (29.23%)	681 (24.82%)	262 (9.55%)	139 (5.07%)
Quintile 1	20 (3.65%)	90 (16.42%)	138 (25.18%)	183 (33.39%)	90 (16.42%)	27 (4.93%)
Quintile 2	21 (3.82%)	113 (20.55%)	154 (28.00%)	168 (30.55%)	73 (13.27%)	21 (3.82%)
Quintile 3	35 (6.39%)	143 (26.09%)	168 (30.66%)	146 (26.64%)	37 (6.75%)	19 (3.47%)

Hospital Characteristic	1	2	3	4	5	N/A
Quintile 4	46 (8.36%)	141 (25.64%)	185 (33.64%)	107 (19.45%)	41 (7.45%)	30 (5.45%)
Quintile 5	97 (17.70%)	154 (28.10%)	157 (28.65%)	77 (14.05%)	21 (3.83%)	42 (7.66%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)
CAH	1 (0.08%)	37 (2.80%)	225 (17.02%)	328 (24.81%)	55 (4.16%)	676 (51.13%)
Non-CAH	227 (6.95%)	673 (20.62%)	894 (27.39%)	808 (24.75%)	352 (10.78%)	310 (9.50%)
1-99 beds	16 (1.34%)	133 (11.17%)	320 (26.87%)	340 (28.55%)	142 (11.92%)	240 (20.15%)
100-199 beds	52 (5.71%)	232 (25.49%)	284 (31.21%)	222 (24.40%)	84 (9.23%)	36 (3.96%)
200-299 beds	63 (13.24%)	131 (27.52%)	120 (25.21%)	106 (22.27%)	50 (10.50%)	6 (1.26%)
300-399 beds	37 (12.85%)	85 (29.51%)	70 (24.31%)	60 (20.83%)	36 (12.50%)	0 (0%)
400 or more beds	59 (16.03%)	91 (24.73%)	99 (26.90%)	79 (21.47%)	40 (10.87%)	0 (0%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)
Large Urban	115 (8.86%)	294 (22.65%)	320 (24.65%)	289 (22.27%)	150 (11.56%)	130 (10.02%)
Other Urban	89 (7.64%)	245 (21.03%)	306 (26.27%)	290 (24.89%)	139 (11.93%)	96 (8.24%)
Rural	23 (2.99%)	133 (17.27%)	267 (34.68%)	228 (29.61%)	63 (8.18%)	56 (7.27%)
N/A	1 (0.07%)	38 (2.81%)	226 (16.70%)	329 (24.32%)	55 (4.07%)	704 (52.03%)

TABLE 72: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	197 (4.30%)	597 (13.02%)	1037 (22.61%)	1033 (22.53%)	576 (12.56%)	1146 (24.99%)
Specialty	0 (0%)	0 (0%)	5 (4.13%)	8 (6.61%)	23 (19.01%)	85 (70.25%)
Non-Specialty	197 (4.53%)	593 (13.63%)	1022 (23.49%)	1008 (23.17%)	537 (12.34%)	994 (22.85%)
N/A	0 (0%)	4 (3.51%)	10 (8.77%)	17 (14.91%)	16 (14.04%)	67 (58.77%)
Major Teaching	27 (11.20%)	54 (22.41%)	74 (30.71%)	58 (24.07%)	27 (11.20%)	1 (0.41%)
Minor Teaching	94 (6.55%)	259 (18.05%)	409 (28.50%)	386 (26.90%)	174 (12.13%)	113 (7.87%)
Non-Teaching	76 (2.72%)	280 (10.01%)	544 (19.46%)	572 (20.46%)	359 (12.84%)	965 (34.51%)
N/A	0 (0%)	4 (3.51%)	10 (8.77%)	17 (14.91%)	16 (14.04%)	67 (58.77%)
Safety-Net	79 (5.96%)	159 (12.00%)	234 (17.66%)	222 (16.75%)	116 (8.75%)	515 (38.87%)
Non-Safety-Net	118 (3.79%)	430 (13.80%)	782 (25.10%)	783 (25.13%)	442 (14.18%)	561 (18.00%)
N/A	0 (0%)	8 (5.52%)	21 (14.48%)	28 (19.31%)	18 (12.41%)	70 (48.28%)
Non-DSH	5 (1.02%)	25 (5.11%)	81 (16.56%)	124 (25.36%)	105 (21.47%)	149 (30.47%)
DSH	171 (6.23%)	527 (19.21%)	848 (30.90%)	725 (26.42%)	298 (10.86%)	175 (6.38%)
Quintile 1	17 (3.10%)	74 (13.50%)	129 (23.54%)	198 (36.13%)	96 (17.52%)	34 (6.20%)
Quintile 2	15 (2.73%)	91 (16.55%)	167 (30.36%)	174 (31.64%)	77 (14.00%)	26 (4.73%)

Hospital Characteristic	1	2	3	4	5	N/A
Quintile 3	23 (4.20%)	106 (19.34%)	201 (36.68%)	139 (25.36%)	55 (10.04%)	24 (4.38%)
Quintile 4	25 (4.55%)	121 (22.00%)	197 (35.82%)	127 (23.09%)	42 (7.64%)	38 (6.91%)
Quintile 5	91 (16.61%)	135 (24.64%)	154 (28.10%)	87 (15.88%)	28 (5.11%)	53 (9.67%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)
CAH	19 (1.44%)	44 (3.33%)	108 (8.17%)	184 (13.92%)	173 (13.09%)	794 (60.06%)
Non-CAH	178 (5.45%)	553 (16.94%)	929 (28.46%)	849 (26.01%)	403 (12.35%)	352 (10.78%)
1-99 beds	19 (1.60%)	105 (8.82%)	261 (21.91%)	318 (26.70%)	205 (17.21%)	283 (23.76%)
100-199 beds	44 (4.84%)	180 (19.78%)	310 (34.07%)	251 (27.58%)	90 (9.89%)	35 (3.85%)
200-299 beds	50 (10.50%)	105 (22.06%)	144 (30.25%)	120 (25.21%)	51 (10.71%)	6 (1.26%)
300-399 beds	30 (10.42%)	74 (25.69%)	90 (31.25%)	75 (26.04%)	19 (6.60%)	0 (0%)
400 or more beds	33 (8.97%)	88 (23.91%)	124 (33.70%)	85 (23.10%)	38 (10.33%)	0 (0%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)
Large Urban	107 (8.24%)	242 (18.64%)	349 (26.89%)	309 (23.81%)	156 (12.02%)	135 (10.40%)
Other Urban	48 (4.12%)	197 (16.91%)	361 (30.99%)	313 (26.87%)	140 (12.02%)	106 (9.10%)
Rural	21 (2.73%)	113 (14.68%)	219 (28.44%)	227 (29.48%)	107 (13.90%)	83 (10.78%)
N/A	21 (1.55%)	45 (3.33%)	108 (7.98%)	184 (13.60%)	173 (12.79%)	822 (60.75%)

TABLE 73: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITHOUT READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	184 (4.01%)	620 (13.52%)	1026 (22.37%)	1051 (22.92%)	559 (12.19%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	6 (4.96%)	9 (7.44%)	20 (16.53%)	85 (70.25%)
Non-Specialty	184 (4.23%)	612 (14.07%)	1006 (23.12%)	1029 (23.65%)	526 (12.09%)	994 (22.85%)
N/A	0 (0%)	7 (6.14%)	14 (12.28%)	13 (11.40%)	13 (11.40%)	67 (58.77%)
Major Teaching	24 (9.96%)	45 (18.67%)	72 (29.88%)	64 (26.56%)	35 (14.52%)	1 (0.41%)
Minor Teaching	86 (5.99%)	249 (17.35%)	380 (26.48%)	386 (26.90%)	221 (15.40%)	113 (7.87%)
Non-Teaching	74 (2.65%)	319 (11.41%)	560 (20.03%)	588 (21.03%)	290 (10.37%)	965 (34.51%)
N/A	0 (0%)	7 (6.14%)	14 (12.28%)	13 (11.40%)	13 (11.40%)	67 (58.77%)
Safety-Net	73 (5.51%)	188 (14.19%)	236 (17.81%)	229 (17.28%)	84 (6.34%)	515 (38.87%)
Non-Safety-Net	111 (3.56%)	421 (13.51%)	767 (24.61%)	798 (25.61%)	458 (14.70%)	561 (18.00%)
N/A	0 (0%)	11 (7.59%)	23 (15.86%)	24 (16.55%)	17 (11.72%)	70 (48.28%)
Non-DSH	5 (1.02%)	28 (5.73%)	87 (17.79%)	111 (22.70%)	109 (22.29%)	149 (30.47%)
DSH	161 (5.87%)	500 (18.22%)	775 (28.24%)	757 (27.59%)	376 (13.70%)	175 (6.38%)
Quintile 1	17 (3.10%)	72 (13.14%)	117 (21.35%)	185 (33.76%)	123 (22.45%)	34 (6.20%)
Quintile 2	12 (2.18%)	86 (15.64%)	150 (27.27%)	180 (32.73%)	96 (17.45%)	26 (4.73%)
Quintile 3	21 (3.83%)	96 (17.52%)	180 (32.85%)	149 (27.19%)	78 (14.23%)	24 (4.38%)

Hospital Characteristic	1	2	3	4	5	N/A
Quintile 4	26 (4.73%)	111 (20.18%)	180 (32.73%)	145 (26.36%)	50 (9.09%)	38 (6.91%)
Quintile 5	85 (15.51%)	135 (24.64%)	148 (27.01%)	98 (17.88%)	29 (5.29%)	53 (9.67%)
N/A	18 (1.33%)	92 (6.80%)	164 (12.12%)	183 (13.53%)	74 (5.47%)	822 (60.75%)
CAH	16 (1.21%)	91 (6.88%)	164 (12.41%)	183 (13.84%)	74 (5.60%)	794 (60.06%)
Non-CAH	168 (5.15%)	529 (16.21%)	862 (26.41%)	868 (26.59%)	485 (14.86%)	352 (10.78%)
1-99 beds	23 (1.93%)	131 (11.00%)	257 (21.58%)	298 (25.02%)	199 (16.71%)	283 (23.76%)
100-199 beds	42 (4.62%)	154 (16.92%)	277 (30.44%)	274 (30.11%)	128 (14.07%)	35 (3.85%)
200-299 beds	47 (9.87%)	96 (20.17%)	133 (27.94%)	121 (25.42%)	73 (15.34%)	6 (1.26%)
300-399 beds	27 (9.38%)	70 (24.31%)	83 (28.82%)	75 (26.04%)	33 (11.46%)	0 (0%)
400 or more beds	27 (7.34%)	77 (20.92%)	112 (30.43%)	100 (27.17%)	52 (14.13%)	0 (0%)
N/A	18 (1.33%)	92 (6.80%)	164 (12.12%)	183 (13.53%)	74 (5.47%)	822 (60.75%)
Large Urban	101 (7.78%)	220 (16.95%)	332 (25.58%)	305 (23.50%)	205 (15.79%)	135 (10.40%)
Other Urban	42 (3.61%)	185 (15.88%)	318 (27.30%)	343 (29.44%)	171 (14.68%)	106 (9.10%)
Rural	23 (2.99%)	123 (15.97%)	212 (27.53%)	220 (28.57%)	109 (14.16%)	83 (10.78%)

TABLE 74: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITHOUT PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	122 (2.66%)	555 (12.10%)	1078 (23.51%)	1101 (24.01%)	584 (12.73%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	3 (2.48%)	8 (6.61%)	24 (19.83%)	85 (70.25%)
Non-Specialty	122 (2.80%)	551 (12.66%)	1064 (24.45%)	1077 (24.75%)	543 (12.48%)	994 (22.85%)
N/A	0 (0%)	3 (2.63%)	11 (9.65%)	16 (14.04%)	17 (14.91%)	67 (58.77%)
Major Teaching	15 (6.22%)	52 (21.58%)	83 (34.44%)	64 (26.56%)	26 (10.79%)	1 (0.41%)
Minor Teaching	60 (4.18%)	245 (17.07%)	434 (30.24%)	412 (28.71%)	171 (11.92%)	113 (7.87%)
Non-Teaching	47 (1.68%)	255 (9.12%)	550 (19.67%)	609 (21.78%)	370 (13.23%)	965 (34.51%)
N/A	0 (0%)	3 (2.63%)	11 (9.65%)	16 (14.04%)	17 (14.91%)	67 (58.77%)
Safety-Net	51 (3.85%)	157 (11.85%)	236 (17.81%)	245 (18.49%)	121 (9.13%)	515 (38.87%)
Non-Safety-Net	71 (2.28%)	392 (12.58%)	820 (26.32%)	828 (26.57%)	444 (14.25%)	561 (18.00%)
N/A	0 (0%)	6 (4.14%)	22 (15.17%)	28 (19.31%)	19 (13.10%)	70 (48.28%)
Non-DSH	5 (1.02%)	23 (4.70%)	85 (17.38%)	133 (27.20%)	94 (19.22%)	149 (30.47%)
DSH	104 (3.79%)	485 (17.67%)	891 (32.47%)	785 (28.61%)	304 (11.08%)	175 (6.38%)
Quintile 1	12 (2.19%)	70 (12.77%)	136 (24.82%)	203 (37.04%)	93 (16.97%)	34 (6.20%)
Quintile 2	10 (1.82%)	76 (13.82%)	182 (33.09%)	181 (32.91%)	75 (13.64%)	26 (4.73%)
Quintile 3	15 (2.74%)	95 (17.34%)	209 (38.14%)	150 (27.37%)	55 (10.04%)	24 (4.38%)
Quintile 4	12 (2.18%)	113 (20.55%)	203 (36.91%)	141 (25.64%)	43 (7.82%)	38 (6.91%)

Quintile 5	55 (10.04%)	131 (23.91%)	161 (29.38%)	110 (20.07%)	38 (6.93%)	53 (9.67%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)
CAH	11 (0.83%)	46 (3.48%)	102 (7.72%)	183 (13.84%)	186 (14.07%)	794 (60.06%)
Non-CAH	111 (3.40%)	509 (15.59%)	976 (29.90%)	918 (28.13%)	398 (12.19%)	352 (10.78%)
1-99 beds	12 (1.01%)	80 (6.72%)	270 (22.67%)	335 (28.13%)	211 (17.72%)	283 (23.76%)
100-199 beds	26 (2.86%)	159 (17.47%)	327 (35.93%)	279 (30.66%)	84 (9.23%)	35 (3.85%)
200-299 beds	31 (6.51%)	109 (22.90%)	153 (32.14%)	126 (26.47%)	51 (10.71%)	6 (1.26%)
300-399 beds	21 (7.29%)	75 (26.04%)	91 (31.60%)	84 (29.17%)	17 (5.90%)	0 (0%)
400 or more beds	19 (5.16%)	85 (23.10%)	135 (36.68%)	94 (25.54%)	35 (9.51%)	0 (0%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)
Large Urban	68 (5.24%)	227 (17.49%)	384 (29.58%)	332 (25.58%)	152 (11.71%)	135 (10.40%)
Other Urban	27 (2.32%)	188 (16.14%)	372 (31.93%)	335 (28.76%)	137 (11.76%)	106 (9.10%)
Rural	14 (1.82%)	93 (12.08%)	220 (28.57%)	251 (32.60%)	109 (14.16%)	83 (10.78%)
N/A	13 (0.96%)	47 (3.47%)	102 (7.54%)	183 (13.53%)	186 (13.75%)	822 (60.75%)

TABLE 75: DISTRIBUTION OF STAR RATINGS BY HOSPITAL CHARACTERISTICS, COMBINED METHODOLOGY PROPOSALS WITH PEER GROUPING & WITH READMISSION STRATIFICATION BY DUAL-ELIGIBILITY GROUPS

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	145 (3.16%)	567 (12.36%)	1087 (23.70%)	1093 (23.83%)	548 (11.95%)	1146 (24.99%)
Specialty	0 (0%)	1 (0.83%)	5 (4.13%)	12 (9.92%)	18 (14.88%)	85 (70.25%)
Non-Specialty	145 (3.33%)	560 (12.87%)	1069 (24.57%)	1067 (24.52%)	516 (11.86%)	994 (22.85%)
N/A	0 (0%)	6 (5.26%)	13 (11.40%)	14 (12.28%)	14 (12.28%)	67 (58.77%)
Major Teaching	17 (7.05%)	45 (18.67%)	77 (31.95%)	64 (26.56%)	37 (15.35%)	1 (0.41%)
Minor Teaching	72 (5.02%)	236 (16.45%)	405 (28.22%)	401 (27.94%)	208 (14.49%)	113 (7.87%)
Non-Teaching	56 (2.00%)	280 (10.01%)	592 (21.17%)	614 (21.96%)	289 (10.34%)	965 (34.51%)
N/A	0 (0%)	6 (5.26%)	13 (11.40%)	14 (12.28%)	14 (12.28%)	67 (58.77%)
Safety-Net	57 (4.30%)	161 (12.15%)	268 (20.23%)	243 (18.34%)	81 (6.11%)	515 (38.87%)
Non-Safety-Net	88 (2.82%)	397 (12.74%)	796 (25.55%)	825 (26.48%)	449 (14.41%)	561 (18.00%)
N/A	0 (0%)	9 (6.21%)	23 (15.86%)	25 (17.24%)	18 (12.41%)	70 (48.28%)
Non-DSH	5 (1.02%)	29 (5.93%)	91 (18.61%)	115 (23.52%)	100 (20.45%)	149 (30.47%)
DSH	124 (4.52%)	468 (17.06%)	829 (30.21%)	774 (28.21%)	374 (13.63%)	175 (6.38%)
Quintile 1	15 (2.74%)	69 (12.59%)	127 (23.18%)	190 (34.67%)	113 (20.62%)	34 (6.20%)
Quintile 2	12 (2.18%)	75 (13.64%)	161 (29.27%)	181 (32.91%)	95 (17.27%)	26 (4.73%)
Quintile 3	19 (3.47%)	87 (15.88%)	195 (35.58%)	147 (26.82%)	76 (13.87%)	24 (4.38%)
Quintile 4	16 (2.91%)	108 (19.64%)	188 (34.18%)	148 (26.91%)	52 (9.45%)	38 (6.91%)
Quintile 5	62 (11.31%)	129 (23.54%)	158 (28.83%)	108 (19.71%)	38 (6.93%)	53 (9.67%)

Hospital Characteristic	1	2	3	4	5	N/A
N/A	16 (1.18%)	70 (5.17%)	167 (12.34%)	204 (5.08%)	74 (5.47%)	822 (60.75%)
CAH	14 (1.06%)	69 (5.22%)	167 (12.63%)	204 (15.43%)	74 (5.60%)	794 (60.06%)
Non-CAH	131 (4.01%)	498 (15.26%)	920 (28.19%)	889 (27.24%)	474 (14.52%)	352 (10.78%)
1-99 beds	17 (1.43%)	99 (8.31%)	285 (23.93%)	312 (26.20%)	195 (16.37%)	283 (23.76%)
100-199 beds	31 (3.41%)	153 (16.81%)	292 (32.09%)	272 (29.89%)	127 (13.96%)	35 (3.85%)
200-299 beds	35 (7.35%)	102 (21.43%)	141 (29.62%)	119 (25.00%)	73 (15.34%)	6 (1.26%)
300-399 beds	23 (7.99%)	69 (23.96%)	80 (27.78%)	84 (29.17%)	32 (11.11%)	0 (0%)
400 or more beds	23 (6.25%)	74 (20.11%)	122 (33.15%)	102 (27.72%)	47 (12.77%)	0 (0%)
N/A	16 (1.18%)	70 (5.17%)	167 (12.34%)	204 (15.08%)	74 (5.47%)	822 (60.75%)
Large Urban	78 (6.01%)	213 (16.41%)	364 (28.04%)	313 (24.11%)	195 (15.02%)	135 (10.40%)
Other Urban	32 (2.75%)	181 (15.54%)	332 (28.50%)	344 (29.53%)	170 (14.59%)	106 (9.10%)
Rural	19 (2.47%)	103 (13.38%)	224 (29.09%)	232 (30.13%)	109 (14.16%)	83 (10.78%)
N/A	16 (1.18%)	70 (.17%)	167 (12.34%)	204 (15.08%)	74 (5.47%)	822 (60.75%)

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a. Alternatives Considered

Overall Hospital Quality Star Rating

We considered a number of alternatives to our proposals discussed in section XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of the preamble of this proposed rule. As described more fully in section E. Current and Proposed Overall Star Rating Methodology, we considered alternatives to measure group weighting, calculation of measure group scores, stratifying the Readmission group based on proportion of dual-eligible patients, and peer grouping by number of measures.

We considered an alternative to equally weight the five measure groups instead of the proposal to weight the four outcome and patient experience measure groups at 22 percent (Morality, Safety of Care, Readmission, and Patient Experience) and the newly proposed Timely and Effective Care process group at 12 percent. Because past stakeholder comments have recommended that outcome groups receive the most weight, we are recommending our proposal but are seeking comment on the alternative presented.

We considered keeping the Latent Variable Model (LVM) as an alternative to the proposed simple average of measure group scores since it is a data driven model where the measure loadings, or measure contribution to the measure group score, are empirically derived and is able to account for sampling variation and missing data. Because past stakeholder comments have indicated that the use of LVM is difficult to understand and the weights of measures and their subsequent impact on the group score changes depending on the underlying data, we proposed to use a simple average of measure group scores but are seeking comment on the alternative presented.

We also considered not stratifying the Readmission measure group based on dual-eligibility peer groups and retaining the current approach, without stratification. This consideration was based on the premise that, although select stakeholders have requested social risk factor adjustment of the

Readmission measure group in alignment with HRRP,[313] other stakeholder groups expressed concern that social risk factor adjustment would be confusing to patients and consumers, resulting in misrepresentation of quality of care at hospitals providing acute inpatient and outpatient care, specifically for dual-eligible patients, while others were concerned that the dual-eligibility variable would not adequately account for social risk in the Overall Star Rating. [314] [315] [316] Furthermore, this consideration was in response to a HHS report titled ''*Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs,*'' submitted to Congress by ASPE, that sets forth new recommendations regarding social risk factors, wherein ASPE does not recommend adjusting quality measure for social risk in public reporting. [317] Due to these considerations, CMS is seeking comment on the alternative to not stratify the Readmission measure group by proportion of dual-eligible patients.

Within the proposal to stratify the Readmission measure group scores based on dual-eligibility peer groups, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating, and not solely based on those participating in HRRP. However, calculating quintiles based on all hospitals would create potential misalignment between HRRP quintiles and Overall Star Rating quintiles, and therefore peer group assignment. Because of this potential misalignment, we propose to recalculate peer group quintiles based on those in the HRRP but we are seeking public comment on our proposal and alternative to recalculate the quintiles based on all hospitals included in the Overall Star Rating.

Finally, we considered not peer grouping by number of measures. Because past stakeholder feedback suggested that CMS consider some type of peer grouping to enable more similar comparisons among hospital types, we proposed to peer group by number of measure groups to achieve this aim. This would enable more similar comparisons among hospitals where smaller hospitals that submit the fewest number of measures are more likely to be in the three measure group peer group and larger hospitals that submit the most measures are more likely to be in the five measure group peer group. We also stated that if we do not finalize our proposal to include CAHs in the Overall Star Ratings, we would not be able to peer group since CAHs make up the majority of the three measure group peer group. Ultimately, we decided to propose peer grouping but are seeking public comment on our proposal as well as the alterative considered to not peer group. We are seeking comment on our alternative considered to not peer group even if we finalize our proposal to include CAHs.

9. Effects of Requirements for the Physician-Owned Hospitals

The physician-owned hospital provisions are discussed in section XIX. of this proposed rule. We propose regulatory updates to the process under which a physician-owned hospital that qualifies as a high Medicaid facility can request an exception to the prohibition on facility expansion. Specifically, we would permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. We would also remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds and the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. We expect these proposals would reduce burden on high Medicaid facilities and give them additional flexibility to expand. Finally, we propose to codify in regulations the policy in an existing frequently asked question that explains CMS' deference to State law for purposes of determining the number of beds for which a hospital is licensed. This proposal reflects current policy, so we do not anticipate that it would have an impact.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assumed that the number of commenters on this CY 2020 OPPS/ASC proposed rule (3,400) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing proposed rule. It is possible that not all commenters will review proposed rule in detail, and it is also possible that some reviewers will choose not to comment on proposed rule. Nonetheless, we believed that the number of commenters on the CY 2020 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of proposed rule. We welcome any comments on the approach in estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and the final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the 2019 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of proposed rule. For each facility that reviewed proposed rule, the estimated cost is $885.92 (8 hours × $110.74). Therefore, we estimated that the total cost of reviewing proposed rule is $3,413,450 ($885.92 × 3,853 reviewers on the CY 2020 proposed rule).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses

[313] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov.*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[314] Ibid.

[315] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[316] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org*: *http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[317] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule will increase payments to small rural hospitals by approximately 3 percent; therefore, it should not have a significant impact on approximately 586 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $156 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this proposed rule, will be a regulatory action for the purposes of Executive Order 13771. We estimate that this proposed rule will generate $2.5 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

H. Conclusion

The changes we are making in this proposed rule will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2021. Table 67 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 2.5 percent increase in payments for all services paid under the OPPS in CY 2021, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, the finalized off-campus provider-based department clinic visits payment policy, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2021.

The updates we propose to the ASC payment system for CY 2020 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 68 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.6 percent for CY 2020.

XXV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 67 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 2.2 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.27 is amended by revising paragraph (a)(1)(iv)(D) and removing paragraph (a)(1)(iv)(E).

The revision reads as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(D) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively and may be provided by the physician remotely using audio/video real-time communications technology.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

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

■ 4. Section 411.362 is amended—

■ a. In paragraph (a), by revising the definition of ''Baseline number of operating rooms, procedure rooms, and beds'';

■ b. By revising paragraphs (c)(1) and (c)(6) introductory text.

The revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

* * * * *

(c) * * *

(1) *General.* An applicable hospital may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request. A high Medicaid facility may request an exception from the prohibition on facility expansion at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision.

* * * * *

(6) *Permitted increase in facility capacity.* With respect to an applicable hospital only, a permitted increase under this section—

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 5. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 412.190 is added to subpart I to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

(a) *Purpose.* (1) The Overall Hospital Quality Star Rating (Overall Star Rating) is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals.

(2) The guiding principles of the Overall Star Rating are as follows. In developing and maintaining the Overall Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with *Hospital Compare* or its successor website and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Star Rating; and

(iv) be responsive to stakeholder input.

(b) *Data included in Overall Star Rating*—(1) *Source of data.* The Overall Star Rating is calculated based on measure data collected and publicly reported on *Hospital Compare* or its successor site under the following CMS hospital inpatient and outpatient programs:

(i) Hospital Inpatient Quality Reporting (IQR) Program—section 1886(b)(3)(B)(viii)(VII) of the Act.

(ii) Hospital-Acquired Condition Reduction Program—section 1886(p)(6)(A) of the Act.

(iii) Hospital Value-based Purchasing Program—section 1886(o)(10)(A) of the Act.

(iv) Hospital Readmissions Reduction Program—section 1886(q)(6)(A) of the Act.

(v) Hospital Outpatient Quality Reporting (OQR) Program—section 1833(t)(17)(e) of the Act.

(2) *Hospitals included in Overall Star Rating.* Subsection (d) hospitals subject to the CMS quality programs specified in paragraph (b)(1) of this section that also have their data publicly reported on one of CMS' websites are included in the Overall Star Rating.

(3) *Critical Access Hospitals.* Critical Access Hospitals (CAHs) that wish to be voluntarily included in the Overall Star Rating must have elected to—

(i) Voluntarily submit quality measures included in and as specified under CMS hospital programs; and

(ii) Publicly report their quality measure data on *Hospital Compare* or its successor site.

(c) *Frequency of publication and data used.* The Overall Star Rating are published once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year.

(d) *Methodology*—(1) *Selection of measures.* Measures are selected from those publicly reported on *Hospital Compare* or its successor website through certain CMS quality programs under paragraph (b)(1) of this section.

(i) From this group of measures, measures falling into one or more of the below listed exclusions will be removed from consideration:

(A) Measures that 100 hospitals or less publicly report. These measures

would not produce reliable measure group scores based on too few hospitals.

(B) Measures that cannot be standardized (as defined in section E.2.d. Measure Score Standardization) and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.

(C) Non-directional measures for which it is unclear whether a high or lower score is better. These measures cannot be standardized to be combined with other measures and form an aggregate measure group score.

(D) Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs; or

(E) Measures that overlap with another measure in terms of cohort or outcome, including component measures that are part of an already-included composite measure.

(ii) [Reserved]

(2) *Measure Score Standardization.* All measure scores are standardized by calculating Z-scores so that all measures are on a single, common scale to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. This is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure standard deviation in order to standardize measures.

(3) *Grouping measures.* Measures are grouped into one of the five clinical groups as follows:

(i) Mortality.

(ii) Safety of Care.

(iii) Readmission.

(iv) Patient Experience.

(v) Timely and Effective Care.

(4) *Calculate measure group scores.* A score is calculated for each measure group for which a hospital has measure data using a simple average of measure scores, as follows:

(i) Each measure group score is standardized by calculating Z-scores for each measure group so that all measure group scores are centered near zero with a standard deviation of one.

(ii) We then take 100 percent divided by the number of measures reported in a measure group to determine the percentage of each measure's weight;

(iii) The measure weight is then multiplied by the standardized measure score to calculate the measure's weighted score;

(iv) Then, all of the individual measure weighted scores within a measure group are added together to calculate the standardized measure group score.

(v) Applicable to the Readmission group only, CMS will stratify hospitals into peer groups based on the proportion of dual-eligible patients at each hospital, using peer groups annually designated by the Hospital Readmissions Reduction Program (HRRP), to calculate the hospitals' Readmission measure group score. Hospitals that do not participate in HRRP would be assigned to one of the peer groups based on their proportion of dual-eligible patients, as they would not have already been assigned to a peer group through the HRRP. If the proportion of dual-eligible patients at each hospital is missing or unavailable, CMS will not assign the hospital to a peer group or adjust their measure group score.

(5) *Reporting thresholds.* In order to receive an Overall Star Rating, a hospital must report at least three measures within at least three measure groups, one of which must specifically be the Mortality or Safety of Care outcome group.

(6) *Hospital Summary Score.* A summary score is calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores.

(i) *Standard Measure Group Weighting.* (A) Each of the Mortality, Safety of Care, Readmission, and Patient Experience groups are weighted 22 percent; and

(B) The Timely and Effective Care group is weighted 12 percent.

(ii) *Reweighting.* (A) Hospitals may have too few cases to report particular measures and, in those cases, may not report enough measures in one or more measure groups.

(B) When a hospital does not have enough measures in one or more measure groups due to too few cases CMS may re-distribute one or more of the missing measure group's weight proportionally across the remaining measure groups by subtracting the standard weight percentage of the group or groups with insufficient measures from 100 percent; and then dividing the resulting percentage across the remaining measure groups, giving new re-proportioned weights.

(7) *Peer grouping.* Hospitals are assigned to one of three peer groups based on the number of measure groups for which they report at least three measures: Three, four, or five measure groups.

(8) *Star ratings assignment.* Hospitals in each peer group are then assigned between one and five stars where one star is the lowest and five stars is the highest using k-means clustering to complete convergence.

(e) *Preview period prior to publication.* CMS provides hospitals the opportunity to preview their Overall Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Star Rating*—(1) *Subsection (d) hospitals.* CMS may consider suppressing Overall Star Rating for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or

(iii) If a Public Health Emergency substantially affects the underlying measure data.

(2) *CAHs.* (i) CAHs may request to withhold their Overall Star Rating from publication on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period.

(ii) CAHs may request to have their Overall Star Rating withheld from publication on *Hospital Compare* or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh data used to calculate the Overall Star Ratings.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 7. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 8. Section 414.510 is amended by revising paragraph (b)(5) introductory text to read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

* * * * *

(b) * * *

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under

paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, or a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, the date of service of the test must be the date the test was performed only if—

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 9. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 10. Section 416.166 is amended by revising paragraph (c)(6) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(c) * * *

(6) Are designated as requiring inpatient care under § 419.22(n) of this chapter as of December 31, 2020;

* * * * *

■ 11. Section 416.310 is amended—

■ a. In paragraphs (a)(2) and (b), by removing the phrase ''data collection time period'' and adding in its place ''data collection period'';

■ b. By revising paragraph (c)(1)(i);

■ c. In paragraph (c)(1)(ii), by removing the phrase ''data collection time period'' and adding in its place ''data collection period'' and removing the phrase ''time period'' and adding in its place ''period'';

■ d. By adding paragraph (c)(1)(iii);

■ e. In paragraph (c)(2), by removing the phrase ''data collection time period'' and adding in its place ''data collection period''; and

■ f. By adding paragraph (f).

The revision and additions read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet website for all web-based measures submitted via a CMS online data submission tool. A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

* * * * *

(f) *Data submission deadlines.* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 12. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 13. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care. Effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

* * * * *

■ 14. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*11*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020 and subsequent years, a multifactor productivity adjustment (as determined by CMS).

* * * * *

■ 15. Section 419.45 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or partial credit is received.

* * * * *

(b) * * *

(1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(3) of this section.

* * * * *

■ 16. Section 419.46 is amended—

■ a. By redesignating paragraphs (a) through (h) as paragraphs (b) through (i), respectively;

■ b. By adding a new paragraph (a);

■ c. By revising newly redesignated paragraphs (b)(2), (c), and (d)(1) and (2);

■ d. In newly redesignated paragraphs (d)(3)(ii) and (iii), by removing the cross-reference to ''paragraph (c)(2)'' and adding in its place ''paragraph (d)(2)'';

■ e. By adding paragraphs (d)(4) and (f)(4);

■ f. By revising newly redesignated paragraph (g)(1);

■ g. In newly redesignated paragraph (g)(2)(viii), by removing the cross-reference to ''paragraph (e)(1)'' and adding in its place ''paragraph (f)(1)'';

■ h. In newly redesignated paragraph (i)(1), by removing the cross-reference ''paragraphs (h)(2) and (3)'' and adding in its place ''paragraphs (i)(2) and (3)'';

■ i. In newly redesignated paragraph (i)(3), by removing the cross-reference ''paragraph (h)(2)'' and adding in its place ''paragraph (i)(2)''; and

■ j. In newly redesignated paragraph (i)(3)(ii) introductory text, by removing the cross-reference ''paragraph (h)(3)(i)(A)'' and adding in its place ''paragraph (i)(3)(i)(A)''.

The additions and revisions read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority.* Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d)

hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures in accordance with the Secretary's requirements.

(b) * * *

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section; and

* * * * *

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet website. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

* * * * *

(4) *Review and corrections period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

* * * * *

(f) * * *

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

■ 17. Section 419.66 is amended by revising paragraph (c)(2)(i) and (ii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) * * *

(i) The device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or

(ii) For devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, a new medical device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

■ 18. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

(i) Blepharoplasty.

(ii) Botulinum toxin injections.

(iii) Panniculectomy.

(iv) Rhinoplasty.

(v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:

(i) Cervical Fusion with Disc Removal.

(ii) Implanted Spinal Neurostimulators.

(3) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

* * * * *

Dated: July 23, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: July 31, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0746; FRL–10010–27–OAR]

RIN 2060–AT85

National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Miscellaneous Organic Chemical Manufacturing source category regulated under national emission standards for hazardous air pollutants (NESHAP). The U.S. Environmental Protection Agency (EPA) is finalizing decisions concerning the RTR, including amendments pursuant to the technology review for equipment leaks and heat exchange systems, and also amendments pursuant to the risk review to specifically address ethylene oxide emissions from storage tanks, process vents, and equipment leaks. In addition, we are taking final action to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding work practice standards for periods of SSM where appropriate, and clarifying regulatory provisions for certain vent control bypasses. The EPA is also taking final action to add monitoring and operational requirements for flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins; add provisions for electronic reporting of performance test results and other reports; and include other technical corrections to improve consistency and clarity. We estimate that these final amendments will reduce hazardous air pollutants (HAP) emissions from this source category by approximately 107 tons per year (tpy) and reduce ethylene oxide emissions from this source category by approximately 0.76 tpy. We also estimate that these final amendments will reduce excess emissions of HAP from flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins by an additional 263 tpy.

DATES: This final rule is effective on August 12, 2020. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register as of August 12, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0746. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. There is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted. For further information and updates on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Ms. Tegan Lavoie, Sector Policies and Programs Division (E–143–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5110; and email address: *lavoie.tegan@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. Matthew Woody, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1535; and email address: *woody.matthew@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Mr. John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACC American Chemistry Council
AEGL acute exposure guideline level
APCD air pollution control device
AMEL Alternative means of emission limitation
ANSI American National Standards Institute
BAAQMD Bay Area Air Quality Management District
Btu/scf British thermal unit per standard cubic foot
CAA Clean Air Act
CAP Chemical Accident Prevention
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CEMS continuous emissions monitoring systems
CFR Code of Federal Regulations
CRA Congressional Review Act
EPA Environmental Protection Agency
EPCRA Emergency Planning and Community Right-To-Know Act
ERT Electronic Reporting Tool
FID flame ionization detector
FTIR fourier transfer infrared spectrometry
gpm gallons per minute
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HES heat exchanger systems
HI hazard index
HON Hazardous Organic NESHAP
HQ hazard quotient
HRVOC highly reactive volatile organic compounds
IBR incorporation by reference
ICR Information Collection Request
IRIS Integrated Risk Information System
kg/yr kilograms per year
km kilometers
lb/yr pounds per year
LDAR leak detection and repair
LEL lower explosive limit
MACT maximum achievable control technology
MCPU miscellaneous organic chemical manufacturing process unit
MIR maximum individual risk
MON Miscellaneous Organic Chemical Manufacturing NESHAP
NAICS North American Industry Classification System
NEI National Emissions Inventory
NESHAP national emission standards for hazardous air pollutants
NHVcz net heating value of the combustion zone gas
NRDC Natural Resources Defense Council
NSPS new source performance standards
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
PB–HAP hazardous air pollutants known to be persistent and bio-accumulative in the environment
PDF portable document format
PDH propane dehydrogenation

PFTIR passive fourier transfer infrared spectrometry
POM polycyclic organic matter
ppm parts per million
ppmv parts per million by volume
ppmw parts per million by weight
PRA Paperwork Reduction Act
PRD pressure relief device(s)
psig pounds per square inch gauge
PSM Process Safety Management
RACT reasonably available control technology
REL reference exposure level
RFA Regulatory Flexibility Act
RTR residual risk and technology review
SCAQMD South Coast Air Quality Management District
SSM startup, shutdown, and malfunction
SV screening value
TAC Texas Administrative Code
TCEQ Texas Commission on Environmental Quality the Court United States Court of Appeals for the District of Columbia Circuit
TOC total organic compound
TOSHI target organ-specific hazard index
tpy tons per year
TRI Toxics Release Inventory
UMRA Unfunded Mandates Reform Act
URE unit risk estimate
VCS voluntary consensus standards
VOC volatile organic compound(s)

Background information. On December 17, 2019 (84 FR 69182), the EPA proposed revisions to the Miscellaneous Organic Chemical Manufacturing NESHAP (MON) based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* in Docket ID No. EPA–HQ–OAR–2018–0746. A ''tracked changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

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K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

NESHAP and Source Category	NAICS [1] code
Miscellaneous Organic Chemical Manufacturing	3251, 3252, 3253, 3254, 3255, 3256, and 3259, with several exceptions.

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the

EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by October 13, 2020. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

On March 13, 2017, the U.S. District Court for District of Columbia ordered the EPA to perform all acts or duties required by CAA section 112(f)(2) and CAA section 112(d)(6) for 20 source categories, including Miscellaneous Organic Chemical Manufacturing, within three years of the date of the court order (See *California Communities Against Toxics, et al.* v. *Scott Pruitt,* 241 F. Supp. 3d 199 (D.D.C. 2017)). On February 19, 2020, the U.S. District Court for District of Columbia granted the EPA an extension on the final rule deadline for the Miscellaneous Organic Chemical Manufacturing source category from March 13, 2020, to May 29, 2020.

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, after consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see 84 FR 69182, December 17, 2019.

B. What is the Miscellaneous Organic Chemical Manufacturing source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the current NESHAP, herein called the Miscellaneous Organic Chemical

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

Manufacturing NESHAP (MON) on November 10, 2003 (68 FR 63852), and further amended the MON on July 1, 2005 (70 FR 38562), and July 14, 2006 (71 FR 40316). The standards are codified at 40 Code of Federal Regulations (CFR) part 63, subpart FFFF. The MON regulates HAP emissions from miscellaneous organic chemical manufacturing process units (MCPUs) located at major sources. An MCPU includes a miscellaneous organic chemical manufacturing process, as defined in 40 CFR 63.2550(i), and must meet the following criteria: (1) It manufactures any material or family of materials described in 40 CFR 63.2435(b)(1); (2) it processes, uses, or generates any of the organic HAP described in 40 CFR 63.2435(b)(2); and, (3) except for certain process vents that are part of a chemical manufacturing process unit, as identified in 40 CFR 63.100(j)(4), the MCPU is not an affected source or part of an affected source under another subpart of 40 CFR part 63. An MCPU also includes any assigned storage tanks and transfer racks; equipment in open systems that is used to convey or store water having the same concentration and flow characteristics as wastewater; and components such as pumps, compressors, agitators, pressure relief devices (PRDs), sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used to manufacture any material or family of materials described in 40 CFR 63.2435(b)(1). Sources of HAP emissions regulated by the MON include the following: process vents, storage tanks, transfer racks, equipment leaks, wastewater streams, and heat exchange systems.

As of November 6, 2018, there were 201 miscellaneous organic chemical manufacturing facilities identified and in operation and subject to the MON standards, herein referred to as ''MON facilities.'' This facility population count was developed using methods described in section II.C of the proposal preamble (84 FR 69182, December 17, 2019). A complete list of known MON facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011).

C. What changes did we propose for the Miscellaneous Organic Chemical Manufacturing source category in our December 17, 2019, RTR proposal?

On December 17, 2019, the EPA published a proposed rule in the **Federal Register** for the MON, 40 CFR part 63, subpart FFFF, that took into consideration the RTR analyses (84 FR 69182). We proposed to find that the risks from the source category are unacceptable. We proposed to address risk by revising the MON pursuant to CAA section 112(f)(2) to require control of ethylene oxide emissions from process vents, storage tanks, and equipment ''in ethylene oxide service.'' [2] We also proposed that these control requirements would both achieve acceptable risks and provide an ample margin of safety to protect public health and more stringent standards are not necessary to prevent an adverse environmental effect.

For process vents, we proposed to either reduce emissions of ethylene oxide by (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight, to a concentration less than 1 part per million by volume (ppmv) for each process vent, or to less than 5 pounds per year (lb/yr) for all combined process vents; or (2) venting emissions through a closed-vent system to a flare meeting the proposed flare operating requirements. For storage tanks, we proposed to reduce emissions of ethylene oxide by either (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight or to a concentration less than 1 ppmv for each storage tank vent; or (2) venting emissions through a closed-vent system to a flare meeting the proposed flare operating requirements. We proposed removing the option to allow use of a design evaluation in lieu of performance testing to demonstrate compliance for both process vents and storage tanks in ethylene oxide service. We also proposed that owners or operators that choose to control emissions with a non-flare control device conduct an initial performance test on each control device in ethylene oxide service to verify performance at the required level of control, and we proposed conducting periodic performance testing on non-flare control devices in ethylene oxide service every 5 years.

To reduce risks from leaking equipment in ethylene oxide service, we co-proposed two options, *i.e.,* Control Option 1 and Control Option 2. In equipment leak co-proposed Control Option 1, we proposed that all light liquid pumps in ethylene oxide service be monitored monthly at a leak definition of 1,000 parts per million (ppm), and when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected. Additionally, under co-proposed Control Option 1, we proposed that the leak repair exemption available for pumps at 40 CFR 63.1026(b)(3), 40 CFR 63.163(c)(3), and 40 CFR 65.107(b)(3) would not apply to equipment in ethylene oxide service. Also, as part of co-proposed Control Option 1, we proposed that all gas/vapor and light liquid connectors in ethylene oxide service be monitored annually at a leak definition of 500 ppm, and when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected. In equipment leak co-proposed Control Option 2, we proposed that more stringent equipment leak standards would apply to the facilities with a maximum individual risk (MIR) greater than 100-in-1 million after imposition of the proposed standards for process vents and storage tanks, as determined by this risk analysis (*i.e.,* Lanxess Corporation and Huntsman Performance). For these two facilities, pumps in ethylene oxide service would be required to be leakless (*i.e.,* have zero emissions) and monitored annually to verify there are no emissions. Additionally, valves in ethylene oxide service would be required to either be leakless and monitored annually or not be leakless and be monitored quarterly. For pumps and valves in ethylene oxide service, we proposed that equipment is considered leaking if an instrument reading above background is found. Furthermore, at

[2] For process vents, we proposed to define ''in ethylene oxide service'' to mean that each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled, undiluted ethylene oxide emissions greater than or equal to 5 lb/yr (2.27 kg/yr). For storage tanks of any capacity and vapor pressure, we proposed to define ''in ethylene oxide service'' to mean that the concentration of ethylene oxide of the stored liquid is greater than or equal to 1 part per million by weight (ppmw). We proposed that the exemptions for ''vessels storing organic liquids that contain HAP only as impurities'' and ''pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere'' listed in the definition of ''storage tank'' at 40 CFR 63.2550(i) do not apply for storage tanks in ethylene oxide service. For the ethylene oxide equipment leak provisions, we proposed to define ''in ethylene oxide service'' to mean any equipment that contains or contacts a fluid (liquid or gas) that is at least 0.1 percent by weight of ethylene oxide.

the two higher risk facilities with a MIR greater than 100-in-1 million, we proposed that connectors in ethylene oxide service would be monitored monthly at a leak definition of 100 ppm. We proposed that when a leak is detected it would be repaired as soon as practicable, but not later than 15 calendar days after it is detected, and a first attempt at repair be made no later than 5 calendar days after the leak is detected. As part of co-proposed Control Option 2, all other facilities with MON equipment in ethylene oxide service would be subject to the standards previously described in equipment leak co-proposed Control Option 1.

In addition, pursuant to the technology review for the Miscellaneous Organic Chemical Manufacturing source category, we proposed that no revisions to the current standards are necessary for process vents, storage tanks, transfer racks, and wastewater streams; however, we did propose changes for equipment leaks and heat exchange systems. We proposed revisions to the equipment leak requirements, pursuant to CAA section 112(d)(6), to lower the leak definition for pumps in light liquid service at existing batch processes from 10,000 ppmv to 1,000 ppmv with monthly monitoring and clarify that you must initially monitor for leaks within 30 days after initial startup of the equipment. In addition, we proposed revisions to the heat exchange system requirements, pursuant to CAA section 112(d)(6), to require owners or operators to use the Modified El Paso Method and repair leaks of total strippable hydrocarbon concentration (as methane) in the stripping gas of 6.2 ppmv or greater.

We also proposed the following amendments:

- Revisions to the operating and monitoring requirements for flares that control ethylene oxide emissions, flares used to control emissions from processes that produce olefins and polyolefins, and providing the option for an owner or operator of a flare outside of this subset to choose to opt in to these revised requirements in lieu of complying with the current flare standards, pursuant to CAA section 112(d)(2) and (3);
- Requirements and clarifications for periods of SSM and bypasses, including for PRD releases, bypass lines on closed vent systems, maintenance activities, and certain gaseous streams routed to a fuel gas system, pursuant to CAA section 112(d)(2) and (3);
- Revisions to the SSM provisions of the MON (in addition to those related to vent control bypasses) in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008), which vacated two provisions that exempted source owners or operators from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM;
- A requirement for electronic submittal of performance test results and reports, performance evaluation reports, and compliance reports;
- Clarifications to the requirements for nonregenerative adsorbers, and regenerative adsorbers that are regenerated offsite;
- IBR of an alternative test method for EPA Method 18 (with caveats);
- IBR of an alternative test method for EPA Method 101A and EPA Method 29 (portion for mercury only);
- IBR of an alternative test method for EPA Method 624;
- Use of an alternative test method for EPA Method 3B (for the manual procedures only and not the instrumental procedures);
- Use of an alternative test method for EPA Method 320 (with caveats); and
- Several minor editorial and technical changes in the subpart.

III. What is included in this final rule?

This action provides the EPA's final determinations pursuant to the RTR provisions of CAA section 112 for the Miscellaneous Organic Chemical Manufacturing source category and amends the MON based on those determinations. This action also finalizes other changes to the NESHAP, including adding requirements and clarifications for periods of SSM and bypasses; revising the operating and monitoring requirements for flares that control ethylene oxide emissions, flares used to control emissions from processes that produce olefins and polyolefins and allowing flares outside of this subset to comply with these amended flare requirements; adding provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports; and other minor editorial and technical changes. This action also reflects several changes to the December 17, 2019, RTR proposal (84 FR 69182), in consideration of comments received during the public comment period as described in section IV of this preamble.

A. What are the final rule amendments based on the risk review for the Miscellaneous Organic Chemical Manufacturing source category?

This section describes the final amendments to the MON being promulgated pursuant to CAA section 112(f). Consistent with the proposal, the EPA determined that the risks for this source category under the current MACT provisions are unacceptable. When risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. As such, the EPA is promulgating final amendments to the MON pursuant to CAA section 112(f)(2) that require control of ethylene oxide for process vents, storage tanks, and equipment in ethylene oxide service, with some changes in the final rule due to comments received during the public comment period. As discussed in section IV.A of this preamble, implementation of these controls will reduce risk to an acceptable level that also provides an ample margin of safety to protect public health. For process vents in ethylene oxide service, the EPA is finalizing the requirement, as proposed, to either reduce emissions of ethylene oxide by (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight, to a concentration less than 1 ppmv for each process vent, or to less than 5 lb/yr for all combined process vents; or (2) venting emissions through a closed-vent system to a flare meeting the flare operating requirements discussed in sections IV.A.1 and IV.C.2 of the proposal preamble (84 FR 69182, December 17, 2019). However, based on comments received on the proposed rulemaking, we are revising the proposed definition of ''in ethylene oxide service'' for process vents by removing ''undiluted'' from the mass-based criteria and removing the phrase ''anywhere in the process.'' In the final rule, a process vent in ethylene oxide service means each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled, ethylene oxide emissions greater than or equal to 5 lb/yr [2.27 kilograms per year (kg/yr)]. In addition, based on comments received on the proposed rulemaking, we are revising the definitions of ''batch process vent'' and ''continuous process vent'' in the final rule to clarify that: (1) The existing 50 ppmv HAP and 200 lb/yr uncontrolled HAP emission cut-offs do not apply to batch process vents in ethylene oxide service; and (2) the existing 0.005 weight percent total organic HAP cut-off in 40 CFR 63.107(d) does not apply to continuous process vents in ethylene oxide service.

For storage tanks in ethylene oxide service, we are finalizing a requirement, as proposed, to reduce emissions of ethylene oxide by either (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight or to a concentration less than 1 ppmv for each storage tank vent; or (2) venting emissions through a closed-vent system to a flare meeting the flare operating requirements discussed in sections IV.A.1 and IV.C.2 of the proposal preamble (84 FR 69182, December 17, 2019). However, based on comments received on the proposed rulemaking, we are revising the proposed definition of ''in ethylene oxide service'' for storage tanks by revising the concentration of ethylene oxide criteria to a 0.1 percent by weight threshold. In the final rule, a storage tank in ethylene oxide service means a storage tank of any capacity and vapor pressure storing a liquid that is at least 0.1 percent by weight of ethylene oxide. We are also finalizing, as proposed, that the exemptions for ''vessels storing organic liquids that contain HAP only as impurities'' and ''pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere'' listed in the definition of ''storage tank'' at 40 CFR 63.2550(i) do not apply for storage tanks in ethylene oxide service.

Additionally, for both process vents in ethylene oxide service and storage tanks in ethylene oxide service, we are removing the option to allow use of a design evaluation in lieu of performance testing to demonstrate compliance to ensure that the required level of control is achieved, consistent with the proposal. We are also finalizing, as proposed, that after promulgation of the rule, owners or operators that choose to control emissions with a non-flare control device conduct an initial performance test according to 40 CFR 63.997 and 40 CFR 63.2450(g) on each existing control device in ethylene oxide service and on each newly installed control device in ethylene oxide service to verify performance at the required level of control. Subsequently, we are finalizing that owners or operators conduct periodic performance testing on non-flare control devices in ethylene oxide service every 5 years. We are also finalizing the proposed requirement for continuous monitoring of operating parameters for scrubbers used to control emissions from process vents in ethylene oxide service or storage tanks in ethylene oxide service, to ensure that the factors needed for the reaction to occur are met (*i.e.,* liquid-to-gas ratio, pressure drop across the scrubber, liquid feed pressure, liquid temperature, and pH), although we are revising the requirement to set the pressure drop across the scrubber and the liquid feed pressure based on the performance test, and instead, we are allowing the limits on these parameters to be based on the manufacturer's recommendations or engineering analysis. Additionally, we are changing the continuous compliance requirements for the operating parameters, such that compliance with the operating parameter limits is determined on an hourly average basis instead of an instantaneous basis.

For equipment leaks, the EPA is promulgating final amendments for co-proposed equipment leak ''Control Option 1'' for controlling emissions from MON equipment in ethylene oxide service, except based on comments received on the proposed rulemaking, in lieu of prohibiting PRDs in ethylene oxide service from releasing directly to the atmosphere, we are clarifying in the final rule that these PRDs must comply with the pressure release management work practice standards proposed at 40 CFR 63.2480(e) and (f). We are also clarifying that any release event from PRDs in ethylene oxide service is a deviation of the standard. The EPA is not finalizing co-proposed equipment leak ''Control Option 2.'' As proposed under equipment leak Control Option 1, we are promulgating the following requirements:

- All light liquid pumps in ethylene oxide service be monitored monthly at a leak definition of 1,000 ppm, and when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected;
- the leak repair exemption available for pumps at 40 CFR 63.1026(b)(3), 40 CFR 63.163(c)(3), and 40 CFR 65.107(b)(3) does not apply to equipment in ethylene oxide service; and
- all gas/vapor and light liquid connectors in ethylene oxide service are required to be monitored annually at a leak definition of 500 ppm, and when a leak is detected, be repaired as soon as practicable, but not later than 15 calendar days after it is detected.

Refer to section IV.C.2 of the proposal preamble (84 FR 69182, December 17, 2019) for further discussion of co-proposed Control Option 1.

Section IV.A.3 of this preamble provides a summary of key comments we received regarding the risk review and our responses.

B. What are the final rule amendments based on the technology review for the Miscellaneous Organic Chemical Manufacturing source category?

For process vents, storage tanks, transfer racks, and wastewater streams in this source category, the EPA is finalizing its proposed determination in the technology review that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards. Therefore, we are not finalizing revisions to the MACT standards for these emission sources under CAA section 112(d)(6).

For leaks from equipment not in ethylene oxide service, we determined that there are developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), we are revising the MACT standards, consistent with the proposed rule (84 FR 69182, December 17, 2019), to lower the leak definition for pumps in light liquid service (in an MCPU that has no continuous process vents and is part of an existing source) from 10,000 ppmv to 1,000 ppmv with monthly monitoring to comply with the requirements in 40 CFR part 63, subpart H or UU, or 40 CFR part 65, subpart F, and to require initial monitoring for equipment leaks within 30 days after initial startup of new or replaced equipment. However, based on comments received on the proposed rulemaking, we are clarifying in the final rule that the initial monitoring of equipment is only required if the new or replaced equipment is subject to Table 6 to 40 CFR part 63, subpart FFFF, and is also subject to periodic monitoring with EPA Method 21 of appendix A–7 to 40 CFR part 60; and that the initial monitoring does not apply to equipment classified as unsafe-to-monitor or difficult-to-monitor equipment.

For heat exchange systems, we determined that there are developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), we are revising the MACT standards, consistent with the proposed rule (84 FR 69182, December 17, 2019), to include revisions to the heat exchange system requirements to require owners or operators to use the Modified El Paso Method and repair leaks of total strippable hydrocarbon concentration (as methane) in the stripping gas of 6.2 ppmv or greater. However, based on

comments received on the proposed rulemaking, we are also making some technical clarifications to allow compliance with the Modified El Paso Method using an alternative mass-based leak action level of total strippable hydrocarbon equal to or greater than 0.18 kilograms per hour (instead of the proposed concentration-based leak action level) for small heat exchange systems with a recirculation rate of 10,000 gallons per minute (gpm) or less. We are also finalizing the proposed specification that none of the heat exchange system requirements apply to heat exchange systems that have a maximum cooling water flow rate of 10 gpm or less.

Section IV.B.3 of this preamble provides a summary of key comments we received on the technology review and our responses.

C. What are the final rule amendments pursuant to CAA section 112(d)(2) and (3) and 112(h) for the Miscellaneous Organic Chemical Manufacturing source category?

Consistent with *Sierra Club* v. *EPA* 551 F. 3d 1019 (D.C. Cir. 2008) and the December 17, 2019, RTR proposal (84 FR 69182), we are revising monitoring and operational requirements for flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins (with the option for an owner or operator of a flare outside of this subset to choose to opt in to the proposed requirements in lieu of complying with the current flare standards) to ensure these flares meet the MACT standards at all times when controlling HAP emissions. However, based on comments received on the proposed rulemaking, we are not finalizing the work practice standard for velocity exceedances for flares operating above their smokeless capacity. We are also clarifying in the final rule that a ''flare that controls ethylene oxide emissions'' is a flare that controls ethylene oxide emissions from affected sources in ethylene oxide service as defined in 40 CFR 63.2550. In addition, we are clarifying in the final rule that ''an MCPU that produces olefins or polyolefins'' includes only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product; conversely, by-products and impurities as defined in 40 CFR 63.101, as well as wastes and trace contaminants, are not considered products.

In addition, we are finalizing provisions and clarifications as proposed for periods of SSM and bypasses, including PRD releases; bypass lines on closed vent systems; maintenance activities; and certain gaseous streams routed to a fuel gas system to ensure that CAA section 112 standards apply continuously.

Lastly, based on comments received on the proposed rulemaking, we are finalizing a separate standard for storage vessel degassing for storage vessels subject to the control requirements in Table 4 to 40 CFR part 63, subpart FFFF.

Section IV.C.3 of this preamble provides a summary of key comments we received on the CAA section 112(d)(2) and (3) provisions and our responses.

D. What are the final rule amendments addressing emissions during periods of SSM?

We are finalizing the proposed amendments to the MON to remove and revise provisions related to SSM. In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemptions violate the CAA's requirement that some CAA section 112 standards apply at all times. As detailed in section IV.E.1 of the proposal preamble (see 84 FR 69182, December 17, 2019), the MON requires that the standards apply at all times (see 40 CFR 63.2450(a)(2)), consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008). We determined that facilities in this source category can meet the applicable MACT standards at all times, including periods of startup and shutdown. As discussed in the proposal preamble, the EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards, although the EPA has the discretion to set standards for malfunction periods where feasible. Where appropriate, and as discussed in section III.C of this preamble, we are also finalizing alternative standards for certain emission points during periods of SSM to ensure a CAA section 112 standard applies ''at all times.'' Other than for those specific emission points discussed in section III.C of this preamble, the EPA determined that no additional standards are needed to address emissions during periods of SSM. We determined that facilities in this source category can meet the applicable MACT standards at all times, including periods of startup and shutdown.

We are finalizing revisions to the General Provisions table (Table 12 to 40 CFR part 63, subpart FFFF) to eliminate requirements that include rule language providing an exemption for periods of SSM. Additionally, we are finalizing our proposal to eliminate language related to SSM that treats periods of startup and shutdown the same as periods of malfunction. Finally, we are finalizing our proposal to revise reporting and recordkeeping requirements for deviations as they relate to exemptions for periods of SSM. As discussed in section IV.E.1 of the proposal preamble, these revisions are consistent with the requirement in 40 CFR 63.2450(a)(2) that the standards apply at all times. We are also finalizing, as proposed, a revision to the performance testing requirements. The final performance testing provisions prohibit performance testing during SSM because these conditions are not representative of normal operating conditions. The final rule also requires, as proposed, that operators maintain records to document that operating conditions during the test represent normal operations.

The legal rationale and detailed revisions for SSM periods that we are finalizing here are set forth in the proposal preamble (84 FR 69224–69227, December 17, 2019). Also, based on comments received during the public comment period, we are revising specific references listed in 40 CFR 63.2450(e)(4), 40 CFR 63.2480(f), and 40 CFR 63.2485(p) and (q) to sufficiently address the SSM exemption provisions from subparts referenced by the MON (*e.g.,* the MON references 40 CFR part 63, subparts F, G, SS, UU, WW, and GGG; and each of these referenced subparts have SSM provisions that we are removing in 40 CFR 63.2450(e)(4), 40 CFR 63.2480(f), and 40 CFR 63.2485(p) and (q) for owners or operators that must comply with the MON). In other words, in addition to what we proposed, we are also clarifying that the certain referenced provisions do not apply when demonstrating compliance with the MACT standards, such as phrases like ''other than a start-up, shutdown, or malfunction'' in the recordkeeping and reporting requirements of 40 CFR part 63, subparts SS and UU. We are also not removing as proposed the term ''breakdowns'' in 40 CFR 63.998(b)(2)(i) as we determined based on a public comment that removing the term is unnecessary and could result in inaccurate calculation of parameter values. Finally, we are also not

removing 40 CFR 63.998(d)(1)(ii) in its entirety as proposed because we determined based on a public comment received that these records are used to demonstrate compliance with the bypass provisions and do not apply to SSM. As discussed in section III.C of this preamble, we are also finalizing alternative standards for certain emission points (*i.e.,* emergency flaring, PRDs, maintenance activities, and tank degassing) during periods of SSM to ensure a CAA section 112 standard applies ''at all times.''

Section IV.D.3 of this preamble provides a summary of key comments we received on the SSM provisions and our responses.

E. What other changes have been made to the NESHAP?

This rule also finalizes, as proposed, revisions to several other NESHAP requirements. We describe these revisions in this section as well as other proposed provisions that have changed since proposal.

1. Electronic Reporting

To increase the ease and efficiency of data submittal and data accessibility, we are finalizing, as proposed, a requirement that owners or operators of MON facilities submit electronic copies of certain required flare management plans (being finalized at 40 CFR 63.2450(e)(5)(iv)), compliance reports (being finalized at 40 CFR 63.2520(e)), performance test reports (being finalized at 40 CFR 63.2520(f)), and performance evaluation reports (being finalized at 40 CFR 63.2520(g)) through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). The final rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [3] at the time of the test be submitted in the format generated through the use of the ERT and that other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of continuous emissions monitoring systems (CEMS) measuring relative accuracy test audit pollutants that are supported by the ERT at the time of the test must be submitted in the format generated through the use of the ERT and other performance evaluation results be submitted in PDF using the attachment module of the ERT. For compliance reports, the final rule requires that owners or operators use the appropriate spreadsheet template to submit information to CEDRI. The final version of the template for these reports will be located on the CEDRI website.[4] The final rule requires that flare management plans be submitted as a PDF upload in CEDRI. In addition, in the final rule, we are correcting an error to clarify that compliance reports must be submitted electronically (*i.e.,* through the EPA's CDX using the appropriate electronic report template for this subpart) beginning August 12, 2023, or once the reporting template has been available on the CEDRI website for 1 year, whichever date is later. Furthermore, we are finalizing, as proposed, provisions that allow facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility, *i.e.,* for a possible outage in the CDX or CEDRI or for a *force majeure* event in the time just prior to a report's due date, as well as the process to assert such a claim.

For a more detailed discussion of these final amendments to the MON, see section IV.E.2.b of the proposal preamble (84 FR 69227, December 17, 2019), as well as section VI.C below on compliance with the Paperwork Reduction Act. For a more thorough discussion of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0169).

2. Monitoring for Adsorbers That Cannot Be Regenerated and Regenerative Adsorbers That Are Regenerated Offsite

We are finalizing requirements at 40 CFR 63.2450(e)(7), as proposed, for owners or operators using adsorbers that cannot be regenerated and regenerative adsorbers that are regenerated offsite to use dual (two or more) adsorbent beds in series and conduct monitoring of HAP or total organic compound (TOC) on the outlet of the first adsorber bed in series using a sample port and a portable analyzer or chromatographic analysis. However, we are revising the proposed rule text in this final action to reduce the monitoring frequency in response to public comments. In the final rule, owners or operators will establish the estimated bed life from a design evaluation of the adsorber. The monitoring frequency increases as the remaining bed life decreases. Owners or operators will monitor monthly when remaining bed life is more than 2 months, weekly when remaining bed life is between 2 months and 2 weeks, and daily when remaining bed life is less than 2 weeks.

3. Exemptions for Heat Exchange Systems

To correct a disconnect between having a National Pollutant Discharge Elimination System (NPDES) permit that meets certain allowable discharge limits at the discharge point of a facility (*e.g.,* outfall) and being able to adequately identify a leak, we are finalizing, as proposed, the removal of certain exemptions for once-through heat exchange systems to comply with cooling water monitoring requirements.[5] However, as discussed further in the response to comment document for this rulemaking, we are adding back in exemptions originating from 40 CFR 63.104(a)(1), (2), (5), and (6) that were inadvertently removed in the proposed rule.

4. Minor Clarifications and Corrections

We are finalizing all of the revisions that we proposed for clarifying text or correcting typographical errors, grammatical errors, and cross-reference errors. These editorial corrections and clarifications are summarized in Table 11 of the proposal preamble. See 84 FR 69228, December 17, 2019. We are also including several additional minor clarifying edits in the final rule based on comments received during the public comment period. We did not receive many substantive comments on these other amendments in the Miscellaneous Organic Chemical Manufacturing RTR proposal. The comments and our specific responses to these items can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

[3] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

[4] *https://www.epa.gov/electronic-reporting-air-emissions/cedri.*

[5] Cooling water from a once-through heat exchange system at a petrochemical plant can be mixed with other sources of water (*e.g.,* cooling water used in once-through heat exchange systems in other source categories, stormwater, treated wastewater, etc.) in sewers, trenches, and ponds prior to discharge from the plant. If this point of discharge from the plant is into a ''water of the United States,'' then the facility is required to have a NPDES permit and to meet certain pollutant discharge limits.

F. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on August 12, 2020. New affected sources that commenced construction or reconstruction after December 17, 2019 must comply with all of the standards immediately upon the effective date of the standard, or upon startup, whichever is later.

Existing sources and new affected sources that commenced construction or reconstruction after April 4, 2002, and on or before December 17, 2019, must comply with the amended standards according to the following compliance schedules, with two exceptions: (1) We are revising the General Provisions applicability table (Table 12 to 40 CFR part 63, subpart FFFF) to clarify that for all affected sources, the SSM exemptions contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1) do not apply given the Court vacatur in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008); and (2) electronic reporting of performance test reports and performance evaluations are required, as proposed, upon startup or no later than 60 days after the effective date of the final rule, whichever is later.

- Upon initial startup or on August 12, 2023, whichever is later, for the following amendments: (1) The amendments specified in 40 CFR 63.2445(g), which include all amendments finalized under CAA sections 112(d)(2) and (3) and the heat exchange systems amendments finalized under CAA section 112(d)(6); (2) the amendments related to SSM at 40 CFR 63.2420(e)(4) and 63.2525(j); and (3) the amendments related to electronic reporting of flare management plans at 40 CFR 63.2450(e)(5)(iii) and compliance reports.
- Upon initial startup or on August 12, 2021, whichever is later, for the amendments specified in 40 CFR 63.2445(h), which include the amendments finalized under CAA section 112(d)(6) for equipment leaks *(i.e.,* pumps in light liquid service in an MCPU that has no continuous process vents and is part of an existing source).
- Upon initial startup or on August 12, 2022, whichever is later, for the amendments specified in 40 CFR 63.2445(i), which include amendments finalized under CAA section 112(f) for process vents, storage tanks, and equipment that are in ethylene oxide service.

Except for the compliance schedule for the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1) as previously described in this section of the preamble, these compliance schedules have not changed from proposal. However, we are correcting a typographical error to include the word ''on'' in the phrase ''upon initial startup or on'' of each schedule. We provide a summary in this section of our rationale for the compliance schedule being finalized for existing sources and new affected sources that commenced construction or reconstruction after April 4, 2002, and on or before December 17, 2019. Refer to section IV.F of the proposal preamble (84 FR 69182, December 17, 2019) for additional detail regarding our rationale for the compliance schedules being finalized, with the exception of the compliance schedule for the amendments finalized under CAA section 112(d)(6) for equipment leaks, which is discussed below. We received comments both in support of and in opposition to the proposed compliance schedules. Most commenters generally supported the proposed compliance schedules and said that owners or operators would need a significant period of time to comply with the proposed revisions. Only one commenter objected to the proposed compliance schedules, and primarily argued against the proposed 2-year compliance delay for the amendments made under CAA section 112(f) (for process vents, storage tanks, and equipment that are in ethylene oxide service). Summaries of these comments and the EPA's responses can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

CAA section 112(i) provides that the compliance date shall be as expeditious as practicable, but no later than 3 years after the effective date of the standard. In determining what compliance period is as expeditious as practicable, we consider the amount of time needed to plan and construct projects and change operating procedures. For all amendments being finalized under CAA sections 112(d)(2) and (3), the heat exchange systems amendments being finalized under CAA section 112(d)(6), the amendments related to SSM (except for the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1) as previously described in this section of the preamble), and electronic reporting of flare management plans and compliance reports, we determined that sources will require up to 3 years after August 12, 2020 to comply with the requirements for the following reasons:

- The operating and monitoring requirements for flares being finalized under CAA sections 112(d)(2) and (3) will require the installation of new flare monitoring equipment and likely a new control system to monitor and adjust assist gas addition rates, which will require the flare to be taken out of service and may require a significant portion of the MCPU to be shutdown.
- The work practice standards for atmospheric PRDs in organic HAP service being finalized under CAA sections 112(d)(2) and (3) will necessitate sources to identify the most appropriate preventive measures or control approach; design, install, and test the system; install necessary process instrumentation and safety systems; and may need to time installations with equipment shutdown or maintenance outages.
- The vent control requirements for bypasses being finalized under CAA sections 112(d)(2) and (3) will require the addition of piping and potentially new controls, which will likely be routed to the flare, such that these bypass modifications will need to be coordinated with the installation of the new monitoring equipment for the flares.
- The heat exchange system amendments being finalized under CAA section 112(d)(6) will require engineering evaluations, solicitation and review of vendor quotes, contracting and installation of monitoring equipment, operator training, and updating standard operating procedures.
- The removal of the exemptions from the requirements to meet the standard during SSM periods and the addition of electronic reporting will necessitate reading and understanding these new requirements, evaluation of operations to ensure that they can meet the standards during periods of startup and shutdown, making necessary adjustments to standard operating procedures, and converting reporting mechanisms to install necessary hardware and software. In sum, considering the timeframe needed to come into compliance with all of the removed exemptions in this final rule (which in certain cases, will require installation of complex equipment and system changes for flares), the EPA considers a period of 3 years after the effective date of the final rule to be the most expeditious compliance period practicable.

For the equipment leak amendments being finalized under CAA section 112(d)(6), for pumps in light liquid service (in an MCPU that has no continuous process vents and is part of an existing source), we determined that sources will require up to 1 year after August 12, 2020 because, while the

change to lower the leak definition can be implemented relatively quickly as it requires no additional equipment, it will still require changes to a facilities monitoring program and coordination in monitoring schedules, changes to recordkeeping activities and electronic databases, and changes to reporting forms.

For all amendments being finalized under CAA section 112(f) for process vents in ethylene oxide service, storage tanks in ethylene oxide service, and equipment in ethylene oxide service, we determined that sources will require up to 2 years after August 12, 2020 to comply with the requirements to allow time to plan, purchase, and install equipment for ethylene oxide control. For example, for process vents, if the affected source cannot demonstrate 99.9-percent control of ethylene oxide emissions or reduce ethylene oxide emissions to less than 1 ppmv (from each process vent) or 5 lb/yr (for all combined process vents), then a new control system will need to be installed. Sufficient time will be needed to properly engineer the project, obtain capital authorization and funding, procure the equipment, construct and start-up the equipment, prepare for the initial performance test, set up new software, and develop operating procedures.

IV. What is the rationale for our final decisions and amendments for the Miscellaneous Organic Chemical Manufacturing source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket for this rulemaking.

A. Residual Risk Review for the Miscellaneous Organic Chemical Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(f) for the Miscellaneous Organic Chemical Manufacturing source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the December 17, 2019, proposed rule for 40 CFR part 63, subpart FFFF (84 FR 69182). The results of the risk assessment for the proposal are presented briefly in Table 2 of this preamble. More detail is in the residual risk technical support document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011).

TABLE 2—MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING SOURCE CATEGORY RISK ASSESSMENT RESULTS IN PROPOSAL

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer [2]		Estimated annual cancer incidence (cases per year) [2]	Maximum chronic noncancer TOSHI [2]	Maximum screening acute noncancer HQ
		>100-in-1 million	≥1-in-1 million			
194	2,000	18,000	2,900,000	0.4	1	HQ_{REL} = 6 (acrolein).

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Actual emissions equal allowable emissions; therefore, actual risks equal allowable risks.

The results of the proposed chronic baseline inhalation cancer risk assessment at proposal indicated that, based on estimates of current actual and allowable emissions, the MIR posed by the source category was 2,000-in-1 million driven by ethylene oxide emissions from storage tanks (75 percent), equipment leaks (15 percent), and process vents (8 percent). At proposal, the total estimated cancer incidence from this source category was estimated to be 0.4 excess cancer cases per year, or one case in every 2.5 years. Approximately 2.9 million people were estimated to have cancer risks above 1-in-1 million from HAP emitted from the facilities in this source category. At proposal, the estimated maximum chronic noncancer target organ-specific hazard index (TOSHI) for the source category was 1, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures.

As shown in Table 2 of this preamble, the worst-case acute hazard quotient (HQ) (based on the reference exposure level (REL)) at proposal was 6 based on the REL for acrolein (the next highest dose-response value for acrolein, the acute exposure guideline level–1 (AEGL–1), results in an HQ of 0.2). There were 11 additional instances of acute HQs greater than 1 from the source category. In addition, at proposal, the multipathway risk screening assessment resulted in a maximum Tier 2 cancer screening value (SV) of 10 for polycyclic organic matter (POM) for the farmer scenario. The Tier 2 SVs for all other HAP known to be persistent and bio-accumulative in the environment (PB–HAP) emitted from the source category (mercury compounds, cadmium compounds, and arsenic compounds) were less than 1. The Tier 2 cancer SV for POM means that the maximum cancer risk from exposure to POM emissions through ingestion of farm products is less than 10-in-1 million. At proposal, no site-specific assessment using TRIM.FaTE (which incorporates AERMOD deposition, enhanced soil/water run-off calculations, and model boundary identification) or Tier 3 screening assessment was deemed necessary due to the conservative nature of the Tier 2 screen and the hypothetical construct of the farmer scenario. Also, at proposal, the highest annual average lead concentration of 0.0006 micrograms per cubic meter was well below the National Ambient Air Quality Standards for lead, indicating low potential for multipathway risk of concern due to lead emissions.

At proposal, the maximum lifetime individual cancer risk posed by the 194 modeled facilities, based on whole facility emissions, was 3,000-in-1 million, with ethylene oxide emissions from fugitive emissions and flares from the Synthetic Organic Chemical

Manufacturing, Polyether Polyols Production, and Miscellaneous Organic Chemical Manufacturing source categories driving the risk. Regarding the noncancer risk assessment, the maximum chronic noncancer hazard index (HI) posed by whole facility emissions was estimated to be 7 (for the respiratory system as the target organ), driven by emissions of chlorine and methyl bromide from non-source category sources identified as brominated organic manufacturing.

We weighed all health risk factors, including those shown in Table 2 of this preamble, in our risk acceptability determination and proposed that the risks posed by this source category under the current MACT provisions are unacceptable (section IV.C of the proposal preamble, 84 FR 69182, December 17, 2019). At proposal, we identified ethylene oxide as the driver of the unacceptable risk and evaluated several options to control ethylene oxide emissions from (1) process vents, (2) storage tanks, and (3) equipment ''in ethylene oxide service.'' For process vents, we proposed to define ''in ethylene oxide service'' to mean that each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled, undiluted ethylene oxide emissions greater than or equal to 5 lb/yr (2.27 kg/yr). For storage tanks of any capacity and vapor pressure, we proposed to define ''in ethylene oxide service'' to mean that the concentration of ethylene oxide of the stored liquid is greater than or equal to 1 ppmw. We proposed that the exemptions for ''vessels storing organic liquids that contain HAP only as impurities'' and ''pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere'' listed in the definition of ''storage tank'' at 40 CFR 63.2550(i) do not apply for storage tanks in ethylene oxide service. For the ethylene oxide equipment leak provisions, we proposed to define ''in ethylene oxide service'' to mean any equipment that contains or contacts a fluid (liquid or gas) that is at least 0.1 percent by weight of ethylene oxide.

To reduce risks from process vents in ethylene oxide service, we proposed requirements at 40 CFR 63.2493 to reduce emissions of ethylene oxide by either (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight, to a concentration less than 1 ppmv for each process vent, or to less than 5 lb/yr for all combined process vents; or (2) venting emissions through a closed-vent system to a flare meeting the flare operating requirements discussed in section IV.A.1 of the proposal preamble (84 FR 69182, December 17, 2019).

To reduce risks from storage tanks in ethylene oxide service, we proposed a requirement at 40 CFR 63.2493 to reduce emissions of ethylene oxide by either (1) venting emissions through a closed-vent system to a control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight or to a concentration less than 1 ppmv for each storage tank vent; or (2) venting emissions through a closed-vent system to a flare meeting the flare operating requirements discussed in section IV.A.1 of the proposal preamble (84 FR 69182, December 17, 2019).

To reduce risks from equipment leaks in ethylene oxide service, we co-proposed two control options at 40 CFR 63.2493 (see Table 6 of the proposal preamble, 84 FR 69182, December 17, 2019). In equipment leak co-proposed Control Option 1, we proposed that all light liquid pumps in ethylene oxide service be monitored monthly at a leak definition of 1,000 ppm, and when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected. Additionally, under co-proposed Control Option 1, we proposed that the leak repair exemption available for pumps at 40 CFR 63.1026(b)(3), 40 CFR 63.163(c)(3), and 40 CFR 65.107(b)(3) would not apply to equipment in ethylene oxide service. Also, as part of co-proposed Control Option 1, we proposed that all gas/vapor and light liquid connectors in ethylene oxide service be monitored annually at a leak definition of 500 ppm, and when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected. In equipment leak co-proposed Control Option 2, we proposed that more stringent equipment leak standards would apply to two facilities with a MIR greater than 100-in-1 million (*i.e.,* Lanxess Corporation and Huntsman Performance). For these two facilities, at proposal, light liquid pumps in ethylene oxide service would be required to be leakless (*i.e.,* have zero emissions) and monitored annually to verify there are no emissions; and gas and light liquid valves in ethylene oxide service would be required to either be leakless and monitored annually or not be leakless and be monitored quarterly. For these two facilities, at proposal, light liquid pumps and gas and light liquid valves in ethylene oxide service would be considered leaking if an instrument reading above background is found; and connectors in ethylene oxide service would be monitored monthly at a leak definition of 100 ppm. We proposed that when a leak is detected, it be repaired as soon as practicable, but not later than 15 calendar days after it is detected, and a first attempt at repair be made no later than 5 calendar days after the leak is detected. As part of co-proposed Control Option 2, we proposed all other facilities with MON equipment in ethylene oxide service would be subject to the standards previously described in equipment leak co-proposed Control Option 1.

After implementation of the proposed controls for process vents and storage tanks at MON facilities emitting ethylene oxide, as well as implementation of either of the co-proposed control options for equipment leaks, we proposed that the resulting risks would be acceptable for this source category. We also acknowledged at proposal that estimated post-control risks would be greater than 100-in-1 million (*i.e.,* 200- to 300-in-1 million) and determined that, due to the inherent health protective nature of our risk assessment methods and certain uncertainties,[6] the proposed risk assessment is more likely to overestimate rather than underestimate the risks (see section IV.C.3 of the proposal preamble, 84 FR 69182, December 17, 2019). In our proposal, we presented the risk impacts using health risk measures and information, including the MIR, cancer incidence, population exposed to cancer risks greater than 100-in-1 million, and associated uncertainty in emissions estimates after incremental application of the proposed options to control ethylene oxide emissions from (1) process vents, (2) storage tanks, and (3) equipment in ethylene oxide service (see Table 7 of the proposal preamble, 84 FR 69182, December 17, 2019). At proposal, we determined application of the ethylene oxide-specific controls for process vents and storage tanks would reduce ethylene oxide emissions by an estimated 89 percent for the source category, and the estimated MIR would be reduced from 2,000-in-1 million to 400-in-1 million at Lanxess Corporation, and the next highest estimated MIR would be 300-in-1 million at Huntsman Performance. In both cases, we determined that the remaining risk

[6] Uncertainties regarding the equipment leak emissions, the uncertainties inherent in all risk assessments (*i.e.,* the emissions dataset, dispersion modeling, exposure estimates, and dose-response relationships), and the EPA's use of the 2016 unit risk estimate (URE) for ethylene oxide (which is developed to be health protective).

would be primarily from equipment leak emissions of ethylene oxide. Subsequent application of equipment leak co-proposed Control Option 1 would further reduce ethylene oxide emissions by 4 percent, for a total estimated 93-percent reduction in ethylene oxide emissions for the source category, with the MIR at Lanxess Corporation being further reduced to 200-in-1 million and the MIR at Huntsman Performance remaining at 300-in-1 million. Alternatively, subsequent application of equipment leak co-proposed Control Option 2 (instead of Control Option 1) would reduce ethylene oxide emissions by a total estimated 94-percent for the source category, with the MIR at Lanxess Corporation being further reduced to 100-in-1 million and the MIR at Huntsman Performance being reduced to 200-in-1 million.

At proposal, we requested comments on the use of the 2016 updated URE[7] for ethylene oxide for regulatory purposes beyond those already received for the Hydrochloric Acid (HCl) Production RTR proposed rule (84 FR 1584–1597, February 4, 2019), as well as comments on the use of an alternative URE for ethylene oxide in the final rule for this source category. We also solicited comment on which of the two ethylene oxide equipment leak co-proposed control options should be implemented in the final rulemaking in order to ensure that risks from the source category are acceptable.

We then considered whether the existing MACT standards provide an ample margin of safety to protect public health and whether, taking into consideration costs, energy, safety, and other relevant factors, and whether additional standards are required to prevent an adverse environmental effect. To determine whether the rule provides an ample margin of safety, we considered the requirements that we proposed to achieve acceptable risks. We also considered implementing equipment leak co-proposed Control Option 2, which would require that the two facilities with estimated cancer risks greater than 100-in-1 million comply with more stringent standards. In addition, we considered expanding the applicability of equipment leak co-proposed Control Option 2 so that the more stringent controls would apply to all facilities with equipment in ethylene oxide service, regardless of estimated cancer risks. Finally, we considered the options identified in the technology review (*i.e.,* controls for equipment leaks for MON equipment not in ethylene oxide service and heat exchange systems). In considering whether the standards should be tightened to provide an ample margin of safety to protect public health, we considered the same risk factors that we considered for our acceptability determination and also examined the costs, technological feasibility, and other relevant factors related to emissions control options that might reduce risk associated with emissions from the source category. Based on these considerations, we proposed that the requirements that we proposed to achieve acceptable risks would also provide an ample margin of safety to protect public health (section IV.C.4 of the proposal preamble, 84 FR 69182, December 17, 2019). We also solicited comment on which of the available control options should be applied in order to provide an ample margin of safety to protect public health.

2. How did the risk review change for the Miscellaneous Organic Chemical Manufacturing source category?

a. Miscellaneous Organic Chemical Manufacturing Source Category Risk Assessment

As part of the final risk assessment, the EPA reanalyzed risks using emissions inventory updates that were received from a CAA section 114 request issued to the highest risk facility, and additional information received from the two highest risk facilities during the public comment period. These updates were primarily reductions to emissions of ethylene oxide and included revised actual emissions for two facilities and allowable emissions for one facility. The revised emissions used to reanalyze risks are available in the docket for this rulemaking (see section IV.A.3.b of this preamble and Appendix 1 of the *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* available in the docket for this rulemaking, for more detail about these revised emissions).

Based on the revised actual emission estimates, the results of the chronic inhalation cancer risk from the revised risk assessment indicate that the maximum lifetime individual cancer risk posed by the 194 facilities could be as high as 400-in-1 million, with ethylene oxide from process vents and equipment leaks as the major contributors to the risk. Specifically, the revised baseline cancer risk is reduced to 400-in-1 million for the Lanxess facility, and to less than 100-in-1 million for Huntsman Performance. The total estimated cancer incidence from the revised risk assessment is 0.1 excess cancer cases per year, or one excess case in every 10 years. Of the approximately 89,000,000 people that live within 50 kilometers (km) of the 194 facilities, 1,700,000 people were estimated to have cancer risks greater than or equal to 1-in-1 million from HAP emitted from the facilities in this source category. Approximately 46,000 people were estimated to have cancer risks greater than or equal to 10-in-1 million, and 1,200 people were estimated to have cancer risks greater than or equal to 100-in-1 million. Of those 1,200 people, approximately 860 are estimated to have cancer risks greater than 100-in-1 million (Table 3 of this preamble).

The estimated maximum chronic noncancer TOSHI for the source category remained unchanged from the proposal at 1, indicating low likelihood of adverse noncancer effects from long-term inhalation exposures. Additionally, the worst-case acute HQ (based on the REL) remained unchanged from proposal (6 based on the REL for acrolein and the next highest dose-response value for acrolein, the AEGL–1, results in an HQ of 0.2). Similarly, the multipathway risk screening assessment remained unchanged from proposal and resulted in a maximum Tier 2 cancer SV of 10 for POM for the farmer scenario. The Tier 2 SVs for all other PB–HAP emitted from the source category (mercury compounds, cadmium compounds, and arsenic compounds) were less than 1.

Whole facility risks also did not change from those at proposal based on revised emission estimates. The maximum lifetime individual cancer risk based on whole facility emissions was 3,000-in-1 million driven by ethylene oxide emissions from fugitive emissions and flares from the Synthetic Organic Chemical Manufacturing, Polyether Polyols Production, and Miscellaneous Organic Chemical Manufacturing source categories. The

[7] The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate cancer health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

maximum chronic noncancer HI posed by whole facility emissions was estimated to be 7 (for the respiratory system as the target organ), driven by emissions of chlorine and methyl bromide from non-source category sources identified as brominated organic manufacturing.

Based on revised allowable emission estimates, the maximum lifetime individual cancer risk could be as high as 800-in-1 million, with ethylene oxide from storage tanks, process vents, and equipment leaks driving the risk. The total estimated cancer incidence is 0.2 excess cancer cases per year, or 1 excess case in every 5 years. Approximately 2,000,000 people were estimated to have cancer risks greater than or equal to 1-in-1 million from allowable emissions, approximately 170,000 were estimated to have cancer risks greater than or equal to 10-in-1 million, and 4,200 people were estimated to have cancer risks greater than or equal to 100-in-1 million. Of those 4,200 people, approximately 1,700 are estimated to have cancer risks greater than 100-in-1 million (Table 3 of this preamble).

TABLE 3—MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING SOURCE CATEGORY RISK ASSESSMENT RESULTS BASED ON REVISED EMISSIONS IN FINAL RULE

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer [2]		Estimated annual cancer incidence (cases per year) [2]	Maximum chronic noncancer TOSHI[2]	Maximum screening acute noncancer HQ
		>100-in-1 million	≥1-in-1 million			
Actual Emissions						
194	400	860	1,700,000	0.1	1	HQ_{REL} = 6 (acrolein).
Allowable Emissions						
194	800	1,700	2,000,000	0.2	1	

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] Actual emissions equal allowable emissions with the exception of one facility, where additional information was available.

Finally, risks were estimated after application of the controls finalized in this rulemaking for storage tanks, process vents, and equipment in ethylene oxide service, in addition to controls that apply to all HAP and were identified during the technology review (controls for heat exchangers and equipment leaks for MON equipment not in ethylene oxide service). Based on these controls, we estimated that the baseline cancer MIR of 400-in-1 million would be reduced to 200-in-1 million for actual emissions, with ethylene oxide from equipment leaks driving the risk. There would be 107 people estimated to have a cancer risk greater than 100-in-1 million, down from 860 people in the baseline scenario. There is an estimated reduction in cancer incidence to 0.09 excess cancer cases per year (or one excess case every 11 years), down from 0.1 excess cancer cases per year (or one excess cancer case every 10 years) in the baseline scenario. In addition, the number of people estimated to have a cancer risk greater than or equal to 1-in-1 million would be reduced from 1,700,000 to 1,400,000 (Table 4 of this preamble).

For allowable emissions, we estimated that the baseline cancer MIR of 800-in-1 million would be reduced to 200-in-1 million, with ethylene oxide from equipment leaks driving the risk. There would be 115 people estimated to have a cancer risk greater than 100-in-1 million, down from 1,700 people in the baseline scenario. There is an estimated reduction in cancer incidence to 0.09 excess cancer cases per year (or one excess case every 11 years), down from 0.2 excess cancer cases per year (or one excess cancer case every 5 years) in the baseline scenario. In addition, the number of people estimated to have a cancer risk greater than or equal to 1-in-1 million would be reduced from 2,000,000 to 1,400,000 (Table 4 of this preamble).

TABLE 4—BASELINE AND POST-CONTROL RISK SUMMARY FOR THE MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING SOURCE CATEGORY BASED ON REVISED EMISSIONS IN FINAL RULE

	Inhalation cancer risk		Population cancer risk		
	Maximum individual risk (in 1 million)	Risk driver	Cancer incidence (cases per year)	>100-in-1 million	≥1-in-1 million
Actual Emissions					
Baseline Risk	400	ethylene oxide	0.1	860	1,700,000
Post-control Risk	200	ethylene oxide	0.09	107	1,400,000
Allowable emissions					
Baseline Risk	800	ethylene oxide	0.2	1,700	2,000,000
Post-control Risk	200	ethylene oxide	0.09	115	1,400,000

We continue to find that the revised risks prior to control are unacceptable, and we are revising the final NESHAP for the Miscellaneous Organic Chemical Manufacturing source category pursuant to CAA section 112(f)(2) on the basis that risks are unacceptable. However, as discussed in sections IV.A.3 and IV.A.4 of this preamble, we find that, after implementation of the controls finalized in this rulemaking, the resulting risks would be acceptable for this source category and achieve an ample margin of safety.

Additional details of the reanalyzed risks can be found in the *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* available in the docket for this rulemaking.

b. Rule Changes

Based on comments received on the proposed rulemaking, we are revising the proposed definition of ''in ethylene oxide service'' for process vents by removing ''undiluted'' from mass-based criteria and removing the phrase ''anywhere in the process.'' In the final rule, a process vent in ethylene oxide service means each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled, ethylene oxide emissions greater than or equal to 5 lb/yr (2.27 kg/yr). In addition, based on comments received on the proposed rulemaking, we are revising the definitions of ''batch process vent'' and ''continuous process vent'' in the final rule to clarify that (1) the existing 50 ppmv HAP and 200 lb/yr uncontrolled HAP emission cut-offs do not apply to batch process vents in ethylene oxide service; and (2) the existing 0.005 weight percent total organic HAP cut-off in 40 CFR 63.107(d) does not apply to continuous process vents in ethylene oxide service.

Based on comments received on the proposed rulemaking, we are also revising the proposed definition of ''in ethylene oxide service'' for storage tanks by revising the concentration of ethylene oxide criteria to a 0.1 percent by weight threshold. In the final rule, a storage tank in ethylene oxide service means a storage tank of any capacity and vapor pressure storing a liquid that is at least 0.1 percent by weight of ethylene oxide.

For equipment leaks in ethylene oxide service, we are finalizing the co-proposed equipment leak ''Control Option 1.'' We are not promulgating final amendments for co-proposed equipment leak ''Control Option 2.''

Finally, based on comments received on the proposed rulemaking, we are also revising some of the continuous monitoring requirements for operating parameters for scrubbers used to control emissions from process vents in ethylene oxide service or storage tanks in ethylene oxide service. In the final rule, we are allowing the limits for the pressure drop across the scrubber and the liquid feed pressure to the scrubber to be based on the manufacturer's recommendations or engineering analysis instead of on the performance test. Additionally, we are changing the continuous compliance requirements for the operating parameters, such that compliance with the operating parameter limits is determined on an hourly average basis instead of an instantaneous basis.

3. What key comments did we receive on the risk review, and what are our responses?

This section provides comment summaries and responses for the key comments received regarding the ethylene oxide IRIS URE, including those received for the HCl Production RTR proposed rule (84 FR 1584–1597, February 4, 2019), and our risk assessment for the Miscellaneous Organic Chemical Manufacturing source category, our proposed definition of ''in ethylene oxide service,'' proposed requirements for storage tanks and process vents in ethylene oxide service, and proposed requirements for equipment leaks in ethylene oxide service. We received comments in support of and against the proposed residual risk review, the IRIS URE used in the review, the American Chemistry Council's (ACC's) request for correction under the Information Quality Act asking that the ''NATA risk estimates for E.O.[8] should be withdrawn and corrected to reflect scientifically supportable risk values,'' and our determination that additional controls were warranted under CAA section 112(f)(2) for the Miscellaneous Organic Chemical Manufacturing source category. Other comments on these issues, as well as on additional issues regarding the residual risk review and the EPA's proposed changes based on the residual risk review, can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

a. Ethylene Oxide IRIS URE

In the MON RTR proposed rule (84 FR 69182, December 17, 2019), as well as the HCl Production RTR proposed rule (84 FR 1584, February 4, 2019), we requested comment on the use of the updated ethylene oxide URE for regulatory purposes. Also, in the proposed rulemaking for the Miscellaneous Organic Chemical Manufacturing source category, we noted the ACC's request for correction under the Information Quality Act asking that the ''NATA risk estimates for E.O. should be withdrawn and corrected to reflect scientifically supportable risk values.'' Several commenters provided comments on these two topic areas as summarized below:

Comment: We received extensive comments on use of the EPA ethylene oxide URE. Some commenters were in support of the continued use of the EPA URE and other commenters recommended changes to aspects of the EPA URE or recommended use of an alternative to the EPA URE. Many of the commenters recommending changes to the EPA URE focused on aspects of dose-response modeling that could affect the value of the EPA URE, including model selection, inclusion of breast cancer data, cohort selection, and historical exposure estimates. Other comments evaluated the biological plausibility of the EPA URE, including considerations of endogenous and ambient background ethylene oxide levels and mortality predictions. In some cases, commenters submitted analyses of existing data, including recent publications (*e.g.,* Marsh et al. 2019; Bogen et al. 2019; Kirman and Hays 2017). In addition, the Texas Commission on Environmental Quality (TCEQ) submitted their draft cancer dose-response assessment for ethylene oxide to the EPA for consideration as an alternative to the EPA URE for ethylene oxide.

Response: A number of comments received on aspects of dose-response modeling largely touch on matters that were identified and discussed as part of the peer and public review processes for the EPA IRIS ethylene oxide Assessment, and the Agency considered those comments in the development of the final IRIS ethylene oxide Assessment.[9] The prior comments and responses are documented in the

[8] In this instance, ''E.O.'' refers to ''ethylene oxide.''

[9] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (EtO),* EPA/635/R–16/350fa. Available at *https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730.*

Appendices of the EPA 2016 IRIS ethylene oxide assessment [10] and are therefore addressed here by referencing the existing IRIS responses. For some of these topics, additional comments were submitted that either augment previous comments or address specific details of the final IRIS dose-response model that were not addressed during the peer-review process. For example, additional comments were submitted on pre-1978 exposure estimates and statistical evaluation of the dose-response model selected for lymphoid cancer. Additional detailed responses to these topics are provided in the response to comment document for this rulemaking.

Several public comments referred to recent analyses of existing data, including publications that focus on different aspects of ethylene oxide assessment such as weight of evidence for breast cancer (Marsh et al. 2019), estimates of ethylene oxide levels produced in our bodies (Kirman and Hays 2017), and evaluation of historical occupational exposure estimates (Bogen et al. 2019). As we detail in the response to comment document, consideration of these individual analyses did not prompt the Agency to pursue reassessment of the EPA's IRIS ethylene oxide Assessment for purposes of this rulemaking. For example, Marsh et al. analyzed breast cancer mortality and focused on comparing cancers seen in occupational groups with national or regional average rates; whereas, the EPA has generally focused on studies of breast cancer incidence since many women survive breast cancer.[11] With regard to the amount of ethylene oxide produced within the human body, Kirman and Hays did not include any direct measurements of endogenous ethylene oxide levels; however, they did measure a particular by-product (an adduct—chemical reaction product—with the protein hemoglobin) that could be associated with total ambient exposure (including both endogenous and ambient background) among non-occupationally exposed individuals. While studies of the hemoglobin adduct found it to be a useful marker for high level occupational exposures to ethylene oxide, there are many uncertainties in attempting to use this product as a direct measure of ambient background or endogenous levels of ethylene oxide in the body. Further, because the IRIS URE for ethylene oxide represents the increased cancer risk due to exposure to ethylene oxide emissions above endogenous ethylene oxide and ambient background levels, consideration of the findings of Kirman and Hays or other studies of endogenous or ambient background exposures would not impact the URE. The findings of Bogen et al. are discussed further in the response to comment document for this rulemaking.

Though the TCEQ submitted their draft cancer dose-response assessment for ethylene oxide to the EPA as part of the public comment process, the assessment had not yet undergone peer review, and the TCEQ dose-response value had not yet been finalized by the close of the public comment period for this rulemaking, which closed on March 19, 2020.[12] Therefore, the TCEQ dose-response value could not be considered for this rulemaking.

For these reasons, we have decided to continue to use the EPA URE for ethylene oxide for the risk analyses performed for this final rulemaking. As always, the EPA remains open to new and updated scientific information, as well as new dose response values such as the TCEQ value, as they become available.

Comment: Several commenters supported the ACC's request for correction. Other commenters indicated that there was no justification for a correction to the EPA URE for ethylene oxide.

Response: In a letter to the ACC dated December 18, 2019, the then-acting Assistant Administrator for Air and Radiation stated that ''[b]ecause EPA received comments from the ACC and others on the HCl proposed rule related to use of information in the 2016 EtO IRIS Assessment,'' and ''given that EPA anticipates receiving additional comments focused on the 2016 EtO IRIS Assessment in the MON RTR rulemaking,'' the EPA believed at that time that it was ''appropriate to address this [request for correction] as part of the MON RTR rulemaking.'' [13] Having now reviewed and considered the comments it has received, the EPA has determined that it is appropriate to defer providing a final response to the ACC's request at this time. The EPA is under a court ordered deadline requiring signature of the final MON RTR by May 29, 2020, and we have determined that, given the time available and in light of other resource constraints, completing our consideration of the Information Quality Act request for correction in conjunction with taking final action in this rulemaking is not practicable. Accordingly, in order to ensure that the ACC's request for correction is given the complete attention it warrants, we have determined that it is appropriate to issue this final CAA rule separately from the Agency response to the ACC request. We anticipate taking final action on the Information Quality Act request for correction in the near future.

b. MON Risk Assessment

Several commenters provided comments on specific facilities in the EPA risk assessment and submitted additional data for the EPA to use for assessing public health risks. Those comments are as follows:

Comment: One commenter contended that the EPA conducted a CAA section 114 data collection effort on the highest risk facility, Lanxess, but did not use the data at proposal, even though the results of the performance testing were received in September 2019. The commenter disagreed with the EPA's decision that any changes received by September 2018 were incorporated into the RTR modeling file, and after September 2018 and before February 2019, only minor changes related to MON applicability of ethylene oxide emissions were incorporated into the RTR modeling file. Commenters stated that the EPA has significantly overestimated the risks posed by the Lanxess facility and that if the EPA used the most recent and best available data, the Lanxess facility would not be classified as a high-risk site. As justification, the commenters provided new stack test data for Lanxess' two process scrubbers and the storage tank scrubber based on performance tests conducted from June 3 to June 20, 2019. The commenters provided that the preliminary results from the performance tests indicate that the total ethylene oxide emissions from the three scrubbers were significantly less than the initial estimate that was used for the risk analysis and proposed rule.[14] Commenters observed that the

[10] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (EtO) Appendices,* EPA/635/R–16/350fb. Available at *https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730.*

[11] *Guidelines for Carcinogen Risk Assessment,* EPA/630/P–03/001F, 2005. Available at: *https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.*

[12] Note that the final TCEQ assessment was issued on May 15, 2020.

[13] See Letter from Anne L. Idsal, acting Assistant Administrator for Air and Radiation to William P. Gulledge, American Chemistry Council (December 18, 2019). Similarly, in the proposed rulemaking, we took note of the fact that, ''[g]iven the ACC's Response for Correction,'' we had in the earlier HCl Production RTR proposed rule ''requested comment on the use of the updated ethylene oxide URE for regulatory purposes.'' 84 FR 69218 (December 17, 2019). ''Because of the robustness of the comment received and their relevance to this rulemaking,'' we said that the Agency would ''consider those comments in the final rule for the Miscellaneous Organic Chemical Manufacturing source category.'' *Id.*

[14] Commenter referred to Docket Item No. EPA–HQ–OAR–2018–0746–0022.

risk analysis published at proposal did not include this most recent stack test data.

One commenter also objected to the EPA using a different approach to establish baseline emissions for the Lanxess facility as compared with all other MON facilities and objected to the EPA proposing a more stringent control technology standard specifically for this facility based on incomplete data and a different standard from that which was applied to all other facilities. The commenter reiterated that for the Lanxess facility, the EPA disregarded actual 2014 emissions data for storage tanks and process vents and estimated emissions for fugitives using component counts and emission factors, which the EPA acknowledged likely resulted in emission estimates that were biased high. The commenter provided updated information and requested that the facility emissions, like the other MON facilities, be analyzed based on 2014 actual emissions.

Some commenters requested that the EPA update the emission estimate for the site to reflect a control efficiency of 99.9 percent for the ethylene oxide storage tank scrubber and use 2014 actual emissions data, which would establish a 0.0107 tpy baseline for this scrubber. The commenters further asserted that the EPA chose not to use reported 2014 ethylene oxide emissions associated with the two scrubbers that control emissions from the two process vents in ethylene oxide service and instead calculated potential emission rates using the facility's 2012 title V application, which resulted in a modeling input of almost twice the actual emissions and was not consistent with the method the EPA utilized to review risk for the other MON facilities. The commenters requested that the EPA use the reported values contained in the calendar year 2014 emissions inventory for the two process vent scrubbers to establish the baseline for risk. Commenters further contested the EPA's approach to estimating fugitive emissions and emissions from equipment leaks; commenters did not agree with estimating fugitive emissions based on potential emissions in lieu of 2014 actual emissions. Further, the commenters requested that the EPA update the equipment leak source parameters to a volume source versus an area source to better represent equipment leak emissions, and to update the risk inputs to use current equipment counts, composition of ethylene oxide in the streams, the emission factors from Table 6 of the EPA's equipment leak evaluation memorandum, *Analysis of Control Options for Equipment Leaks at Processes that use ethylene oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* and the facility's actual hours of operation in 2014. The commenters also stated that the facility has no light liquid pumps in ethylene oxide service that would be subject to the proposed pump requirements.

Commenters stated that, using the revised emissions estimates and volume source parameters, they re-ran the EPA's risk model and calculated a baseline risk of 270-in-1 million for the Lanxess facility. The commenter stated that using the revised baseline emissions to estimate post-control emissions would result in significant reductions for either Control Option 1 or 2 and provided revised estimates of post-control emissions based on the updated data. The commenter asserted that when the EPA risk model is rerun for the Lanxess facility utilizing all corrected inputs, the residual risk is 100-in-1 million with implementation of Control Option 1.

Response: In light of the additional data and comments received, the EPA has made adjustments to the emissions used in the residual risk assessment in the final rule, and we note that using revised baseline emissions to estimate post-control emissions results in significant reductions for either Control Option 1 or 2. As we acknowledged in the proposal preamble (84 FR 69186, December 17, 2019), although the EPA did not receive the CAA section 114 data from Lanxess in time to be used at proposal, we posted this data publicly to the docket at proposal to provide the public with sufficient time to review the data and provide comments during the comment period. Further, we acknowledged we intended to ''use the collected information to assist the Agency in filling data gaps, establishing the baseline emissions and control levels for purposes of the regulatory reviews, identifying the most effective control measures, and estimating the environmental impacts associated with the regulatory options considered and reflected.'' (84 FR 69186, December 17, 2019). Thus, as has always been our intent, we are revising the residual risk assessment to incorporate the data received in the response to the CAA section 114 request to update Lanxess' emissions in the final rule, which includes updating emissions for the storage tank and process vents to reflect the measured control efficiencies. Additionally, at proposal, the best available data had us assume that ''actual'' emissions were equal to ''allowable'' emissions. At final, the data acquired from the CAA section 114 request has allowed us to separately estimate ''actual'' emissions and ''allowable'' emissions at Lanxess. Therefore, in the final rule, we present both pre-control and post-control risks for Lanxess considering the range of emissions generated by these two emissions estimations.

Additionally, we are incorporating the updated data for equipment in ethylene oxide service provided during the comment period by Lanxess in the revised risk assessment for the final rule. The updated data include component counts, hours of operation, and percentage of ethylene oxide for each process with equipment in ethylene oxide service. The EPA believes that the updated data represents the best available data because it is more recent and reflects updated component counts and changes made to the process. We considered updating the source parameters for equipment in ethylene oxide service to reflect a volume source as the commenter suggested; however, we ultimately retained the parameters as an area source based on the information already available to the EPA, and after determining such change would have minimal impact on risk. After updating emissions for this facility, the pre-control cancer risks are estimated to be 400-in-1 million (actuals) and 800-in-1 million (allowables). We disagree with the commenter's assertion that pre-control risks are 300-in-1 million based on actual emissions. At proposal and in the commenter's revisions to the modeling file, fugitive ethylene oxide emissions were grouped together and modeled as being released from one location. In their comments, Lanxess provided additional information which made it possible to accurately separate and assign these fugitive ethylene oxide emissions to their actual locations at the facility. In the modeling file for the final rule, we have separated and relocated ethylene oxide fugitive emissions to their proper location, which resulted in a risk higher than what the commenter estimated due to several fugitive areas being in closer proximity to the receptor. Therefore, in the final rule, after considering all updates made to the emissions data for Lanxess, the ethylene oxide emissions at the current level of control (*i.e.,* before the amended controls are applied) are estimated to be approximately 0.64 tpy based on actual emissions and 2.6 tpy based on allowable emissions, compared to 8.8 tpy at proposal. See Appendix 1 of the *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in*

Support of the 2020 Risk and Technology Review Final Rule, available in the docket for this rulemaking, for additional information.

After ethylene oxide-specific controls for process vents, storage tanks, and equipment leak Control Option 1 are applied at Lanxess, ethylene oxide emissions are expected to be reduced to 0.15 tpy based on actual emissions and 0.17 tpy based on allowable emissions. Estimated post-control cancer risks are reduced to 200-in-1 million for both actual and allowable emissions estimates. We disagree with the commenter's assertion that post-control risks at Lanxess after applying controls for process vents, storage tanks, and equipment leak Control Option 1 are 100-in-1 million based on actual emissions, since the commenter did not model fugitive emissions from their actual locations as described above. In addition, Lanxess also provided updated component counts in their comments that we used to update the estimated effect that controls would have in reducing ethylene oxide emissions. These new emission reduction estimates indicate that the revised leak detection and repair (LDAR) requirements for light liquid pumps will have less of an effect in reducing ethylene oxide emissions than estimated at proposal, due to new knowledge that there are no light liquid pumps in ethylene oxide service at Lanxess. After ethylene oxide-specific controls for process vents, storage tanks, and equipment leaks Control Option 2 are applied, and using updated emissions data provided during the comment period, estimated post-control cancer risks are reduced to 100-in-1 million (actuals and allowables).

We note that, after the comment period closed, the EPA met with representatives from Lanxess on March 25, 2020, to discuss their comments posted to the docket on February 20, 2020, (see Docket Item No. EPA–HQ–OAR–2018–0746–0069) and ask clarifying questions. Subsequently, Lanxess provided written responses to these questions on April 17, 2020, as well as additional updates to their February comments that included further revisions to emissions data, which would affect equipment leak emissions estimates. This data was not received in time to incorporate into the final risk modeling; however, we recognize that these changes would further reduce estimated ethylene oxide emissions from equipment leaks. Meeting minutes for the March discussion between the EPA and Lanxess, as well as the written responses Lanxess provided to questions asked at this meeting, can be found in the memorandum, *Meeting Record for March 25, 2020, Meeting Between the U.S. EPA and Representatives of Lanxess Corporation,* in the docket for this rulemaking.

Comment: Several commenters provided input on the emissions estimates used in the risk modeling for the Huntsman Performance facility in Conroe, Texas. One commenter stated that the EPA's emissions estimates for the facility from the 2014 National Emissions Inventory (NEI) and the 2014 Toxics Release Inventory (TRI) are not appropriate for use in a risk assessment. The commenter argued that even if the NEI and TRI data were developed with adequate specificity to support risk modeling, the data are 6 years old and do not reflect current operations. The commenter provided data for the Huntsman Performance facility that they claimed more accurately reflect ethylene oxide emissions from equipment leaks, based on a detailed analysis using direct quarterly LDAR monitoring data for each relevant component. Another commenter recommended that the EPA use the information provided in Huntsman Performance's comments in the final rule because the new data more accurately reflect ethylene oxide emissions at the Huntsman Performance facility. Commenters stressed that the submitted data significantly improve on the 2014 data because they reflect physical and operating changes made since 2014, such as addition and removal of relevant equipment. One commenter explained that the new data submitted remain highly conservative and are expected to overstate actual ethylene oxide emissions, largely because the commenter's data analysis does not assume that results below the detection limit are equal to ''zero'' but are present at the detection limit.

Some commenters stated that the EPA's modeling files incorrectly included sources at the Huntsman Performance facility that are not MON-applicable. One commenter asserted that the EPA's risk assessment for the Huntsman Performance facility incorrectly designates certain units with ethylene oxide emissions as being regulated under MON, despite the fact that they are not MON sources. Commenters also stated that the EPA specifically notes that these ethylene oxide equipment leak emissions are not entirely from MON processes; however, the EPA did not have enough information to distinguish between emissions attributed to MON processes versus other processes (*e.g.,* 40 CFR part 63, subparts H and PPP). The commenter specifically identified the railcar unloading fugitive area and tank farm fugitives as inappropriate to include as MON sources and provided input on why the sources do not meet the definition of MCPU or storage tank or fall within the purview of the MON. The commenter provided a copy of revised modeling they conducted with the updated emissions estimates and removal of units not subject to MON; the commenter's revised modeling results showed that residual risks associated with the Huntsman Performance facility are 40-in-1 million.

Response: The EPA has reviewed the updated equipment leak emissions data provided during the comment period by Huntsman Performance in Conroe, Texas, the second highest risk-driving facility that was identified at proposal. We agree with the information provided that two emission units were incorrectly modeled as being subject to MON, when in fact, they are subject to other standards. As such, in the final rule these units are modeled at the whole facility-level only. We have also updated Huntsman Performance's ethylene oxide equipment leak emissions using the updated emissions data provided by the facility, consistent with the EPA's standard practice of using the best available data. The EPA believes that the updated data represents the best available data because it is more recent (*i.e.,* 2019), is based on actual emissions measurements, reflects recent physical and operating changes made to the process since the 2014 NEI emissions were reported, and conservatively considers results below the detection limit as being present at the detection limit. After considering all updates made to the emissions data for Huntsman Performance, the ethylene oxide emissions before controls are applied are estimated to be approximately 0.03 tpy based on actual and allowable emissions, compared to roughly 0.26 tpy estimated at proposal. The pre-control cancer risks are estimated to be 20-in-1 million. After ethylene oxide-specific controls are applied, the estimated post-control cancer risks are also 20-in-1 million. Risks are not reduced with the amendments because (1) storage tank and process vent controls have no effect since these are not sources of ethylene oxide emissions at this facility, and (2) equipment leak Control Option 1 has no effect because this facility already meets the LDAR requirements this option requires.

We note that, after the comment period closed, the EPA met with representatives from Huntsman Performance on March 12, 2020, to

discuss their comments posted to the docket on February 20, 2020, (see Docket Item No. EPA–HQ–OAR–2018–0746–0073) and ask clarifying questions. Subsequently, Huntsman Performance provided written responses to these questions on April 27, 2020. The information received in their April response further supports their prior assertion from their February 2020 comments that the two units modeled as being subject to MON at proposal should instead be modeled only at the whole facility level and provides additional information related to wastewater operations at the facility. No changes to facility emissions or the risk assessment were made as a result of the April 2020 responses, beyond the changes already made based on their comments submitted in February 2020. Meeting minutes for the referenced discussion between the EPA and Huntsman Performance, as well as the written responses Huntsman Performance provided in April 2020 to the questions asked at this meeting, can be found in the memorandum, *Meeting Record for March 12, 2020, Meeting Between the U.S. EPA and Representatives of Huntsman Performance,* in the docket for this rulemaking.

Several commenters provided comments on the EPA's risk acceptability and ample margin of safety determinations. Those comments are as follows:

Comment: Several commenters agreed with the EPA's determination that the proposed emission standards for this source category would achieve an acceptable risk level and protect public health with an ample margin of safety. One commenter in support of the finding stated that the Benzene NESHAP rulemaking expressly notes that ''[t]he presumptive level provides a benchmark for judging the acceptability of maximum individual risk (''MIR''), but does not constitute a rigid line for making that determination.'' [15] The commenter stated that, in the Benzene NESHAP itself, the EPA found MIRs for two categories that exceeded the standard 1-in-10,000 (100-in-1 million) presumptive benchmark acceptable (200-in-1 million for Coke By-Product Recovery Plants and 600-in-1 million for Equipment Leaks) based on uncertainties in the data that suggested risks were overstated. The commenter expressed that this precedent means that the EPA has authority to accept a MIR that is above a 1-in-10 thousand (100-in-1 million) benchmark, and that scientific uncertainty and the likely overstatement of risks is a reasonable basis for doing so. The commenter stated that, therefore, the EPA should make a similar acceptability determination for the MON RTR rulemaking, given that comparable uncertainties exist with the information and emissions estimates informing the risk modeling.

However, other commenters questioned the justification for proposing a regulation that would still allow a cancer risk of 200- to 300-in-1 million. One commenter stated that failing to set a health-protective emission standard that eliminates unacceptable risk because a risk factor ''could be'' lower is arbitrary and unlawful under CAA section 112(f)(2). Other commenters said they believed that the 100-in-1 million lifetime cancer risk cannot be considered safe or ''acceptable,'' and multiple commenters recommended that the EPA ensure risks from ethylene oxide exposure are below 100-in-1 million. Two commenters insisted that no level of health risks from HAP can be presumed safe or ''acceptable'' and that the EPA must reduce risks to the lowest possible level.

Other commenters stated that the EPA must require companies to take steps necessary to prevent all unacceptable health threats and to provide an ''ample margin of safety to protect public health.'' Commenters further argued that the EPA did not establish an ''ample margin of safety'' between what the EPA considers to be an acceptable level of risk and the current emission limits, taking into account the nature of the chemicals being emitted and the uncertainties in the EPA's risk assessments, as required under CAA section 112(f)(2). The commenter argued that the EPA has not shown that it has considered whether the uncertainties regarding its health risk assessment require a stronger standard.[16]

Response: We agree with commenters that baseline risks for the Miscellaneous Organic Chemical Manufacturing source category were unacceptable. However, we disagree with commenters who objected to our determinations of risk acceptability and ample margin of safety after implementation of proposed controls. As explained in the preamble to the proposed rule (84 FR 69182, December 17, 2019), section 112(f)(2) of the CAA expressly preserves the EPA's use of the two-step process for developing standards to address residual risk and interpret ''acceptable risk'' and ''ample margin of safety'' as developed in the Benzene NESHAP (54 FR 38044, September 14, 1989). As explained in the Benzene NESHAP, ''the first step judgment on acceptability cannot be reduced to any single factor'' and, thus, ''[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information.'' 54 FR 38046, September 14, 1989. Similarly, with regard to the ample margin of safety determination, ''the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.'' *Id.* As also explained in the preamble to the proposed rule (84 FR 69182, December 17, 2019), the EPA has adopted this approach in its residual risk determinations, and the Court has upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP into the statute. See *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

As discussed previously, we have revised the residual risk assessment for the final rule to incorporate additional data received from a CAA section 114 request, as well as updated emissions data for ethylene oxide received during the public comment period, for the two facilities with cancer risks greater than 100-in-1 million at the time of proposal. Revisions to the risk assessment incorporate the best available data and result in an improved assessment of the risks from these sources. The revised risk assessment (documented in the *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking) shows that, both before and after application of Control Option 1, seven of the eight facilities with equipment in ethylene oxide service have estimated cancer risks below the 100-in-1 million benchmark. After application of controls for process vents, storage tanks, and equipment leak Control Option 1 as required by this final rule, the remaining facility,

[15] Commenter provided the following reference: 54 FR 38045, September 14, 1989.

[16] Commenter provided the following reference: *NRDC,* 824 F.2d at 1165 (''Congress . . . recognized in section 112 that the determination of what is 'safe' will always be marked by scientific uncertainty and thus exhorted the Administrator to set emission standards that will provide an 'ample margin' of safety.'').

Lanxess, has estimated cancer risks of 200-in-1 million.

Regarding the post-control cancer risks of 200-in-1-million, based on the revised risk assessment, we note that 100-in-1 million cancer risk is not a bright line indicating that risk is ''acceptable.'' As noted by commenters, the EPA has previously accepted MIRs that exceeded 100-in-1 million (*i.e.,* 200-in-1 million in the Benzene NESHAP, 54 FR 38047; 200-in-1 million in the National Emission Standards for Coke Oven Batteries, 70 FR 19993; and 200-in-1 million in the National Perchloroethylene Air Emissions Standards for Dry Cleaning Facilities, 71 FR 42731). We note that one commenter claimed that the EPA found a cancer risk as high as 600-in-1 million acceptable for equipment leaks in the Benzene NESHAP. This is inaccurate. A 600-in-1 million risk estimate was discussed in the proposed Benzene NESHAP. However, this estimate was found to be based on outdated emissions and, in the final Benzene NESHAP, the EPA noted that while it did not have enough time to do so, if it had estimated risks based on updated emissions information, risks were expected to be approximately 100-in-1 million; this was the basis for the risk acceptability determination (54 FR 38048).

When considering risk acceptability, the EPA considers all of the health risk information and the associated uncertainties (*e.g.,* uncertainties in emissions, relevant health effects information), as well as the inherent health protective nature of our risk assessment methods. For example, many of the dose-response values we use for HAP are considered plausible upper-bound estimates. For the revised risk assessment for this source category, the risk driver was ethylene oxide, and we used the 2016 EPA IRIS URE for ethylene oxide to calculate increased cancer risk. As noted in the preamble to the proposed rule, the modeled cancer risks due to emissions of ethylene oxide are sensitive to the URE applied. For EPA's 2016 ethylene oxide URE, the memorandum, *Sensitivity of Ethylene Oxide Risk Estimates to Dose-Response Model Selection,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0027) and discussed at length in the proposal preamble, highlighted two key aspects (*i.e.,* upper-bound estimate and dose-response model) potentially contributing to the conservative (*i.e.,* health protective) nature of the final 2016 URE. When taken into account, these two aspects provide important context for interpreting risks remaining post-control and indicate that the risks are acceptable.

Furthermore, we note that few people are exposed to cancer risks greater than 100-in-1 million, one of the components of health risk information considered when estimated cancer risks exceed the presumptive benchmark of 100-in-1 million. We estimate that, of the 89,000,000 people living within 50 km of a source category facility, 107 (0.0001 percent) would be exposed to levels greater than 100-in-1 million due to emissions from the source category. We also note that the number of people exposed to risks above 100-in-1 million is similar to other rules where risks above 100-in-1 million were found to be acceptable (100 people in the Benzene NESHAP, 54 FR 38047; 70 people in the National Emission Standards for Coke Oven Batteries, 70 FR 19993; and two people in the National Perchloroethylene Air Emissions Standards for Dry Cleaning Facilities, 71 FR 42731). We also note that the cancer incidence (0.09), while higher than the estimated incidence for Dry Cleaning Facilities (0.002), is comparable to cancer incidence used in acceptability determinations for the Benzene NESHAP (0.05) and for Coke Oven Batteries (0.06), despite considerably more facilities in this source category (194) compared to the others (12, 36, and four facilities, respectively). Also, the percentage of people exposed to cancer risks greater than or equal to 1-in-1 million (2 percent of the population living near a facility) is within the range of other rules such as the Benzene NESHAP (0.4 percent) and Coke Oven Batteries (12 percent).

Finally, no other safe controls were identified to further reduce risks. While equipment leak Control Option 2 for equipment in ethylene oxide service was considered, based on comments and information received on the proposed rule, it would not be appropriate to apply to equipment in ethylene oxide service due to concerns of explosions. Additional details on comments received and our response for equipment leak Control Option 2 are provided in section IV.A.3.c of this preamble.

Therefore, we disagree with commenters that maintain that the EPA should ensure that the MIR is substantially below the presumptive benchmark of 100-in-1 million, or that the EPA must prevent all unacceptable health risks. Considering all of the relevant health risk information and factors discussed in the Benzene NESHAP and presented in the proposal preamble, including the uncertainties discussed in section III of the proposal preamble (*i.e.,* the emissions dataset, dispersion modeling, exposure estimates, and dose-response relationships), the EPA's use of the 2016 IRIS URE for ethylene oxide (which is developed to be health protective), and concerns raised by commenters, we conclude that the risks from HAP emissions for the Miscellaneous Organic Chemical Manufacturing source category, after application of the requirements that we are adopting, including application of the ethylene oxide-specific controls, will achieve acceptable risks for this source category and provide an ample margin of safety to protect human health (consistent with the Benzene NESHAP framework).

c. Rule Changes

Comment: Commenters requested that the EPA reconsider the ethylene oxide thresholds for storage tanks and process vents identified in the proposed definition of ''in ethylene oxide service'' because the thresholds the EPA has proposed for defining process vents and storage tanks in ethylene oxide service would encompass far more storage tanks and process vents than the EPA has accounted for in the rulemaking record. The commenters explained that ethylene oxide is used as a reactant/intermediate in the production of a wide variety of chemicals. The commenters added that because these chemicals are made with ethylene oxide, they may contain small residual amounts of unreacted ethylene oxide at concentrations much less than 0.1 percent. The commenters said that even such low amounts of ethylene oxide would represent ''knowledge that ethylene oxide could be present'' in a number of process vents and storage tanks far beyond the number of facilities identified in the rulemaking record. The commenters stated that if finalized the requirement would likely result in a significant number of storage tanks being subject to the ethylene oxide requirements for which the EPA did not estimate the costs of control or other compliance burden in their impacts analysis. Instead, the commenters recommended revising the threshold to 0.1 percent by weight for storage tanks; and noted that setting the concentration threshold to 0.1 percent by weight as an annual average is consistent with the ''de minimis'' concentration threshold applicable to toxic chemical release reporting under 40 CFR part 372 and the hazardous chemical inventory reporting requirements under the Emergency Planning and Community Right-To-Know Act (EPCRA). The commenters stated that suppliers are not required to inform receiving companies of the

potential presence of ethylene oxide at levels in the 1 ppmw to 1,000 ppmw (0.1 percent) range; and facilities routinely report under these programs and that standardizing the definition of ''in ethylene oxide service'' will allow facilities to continue to use their current chemical inventory tracking systems to determine whether ethylene oxide could potentially be present.

Some commenters also supported revising the threshold to 0.1 percent by weight for process vents. Other commenters supported regulating process vents where the concentration of ethylene oxide exceeds 20 ppmv on an annual average basis at the point of discharge to the atmosphere or the point of entry into a control device. The commenters noted that setting a 20 ppmv threshold for a vent to be considered as being in ethylene oxide service would still be sufficiently protective and would require what are now Group 2 continuous or batch process vents to be controlled. Some commenters also suggested raising the 5 lb/yr mass threshold and clarifying where process vent characteristics should be determined (after the last recovery device but prior to the inlet of any control device that is present and prior to release to the atmosphere). Several commenters objected to the phrase in the proposed rule definition of ''in ethylene oxide service'' as it relates to process vents that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide ''anywhere in the process,'' and when combined, the sum of all these process vents would emit uncontrolled, ''undiluted'' ethylene oxide emissions greater than or equal to 5 lb/yr (2.27 kg/yr). Commenters questioned the use of the term ''undiluted'' as part of the mass emission criteria. One commenter also asked for clarification that some process vents may remain uncontrolled as long as the ethylene oxide from all process vents (controlled and uncontrolled) is less than 5 lb/yr and also asked the EPA to clarify that the 5 lb/yr is on an MCPU-by-MCPU basis.

Response: After consideration of these comments, we agree that storage tanks containing less than 1,000 ppmw of ethylene oxide (less than 0.1 percent by weight) should not be considered in ethylene oxide service. We agree that a 1,000 ppmw threshold that also corresponds to the chemical inventory reporting requirements under EPCRA and other supplier notification requirements does reduce the uncertainty for the regulated community and eliminates the burden of performing analyses to demonstrate compliance with the rule, while preserving the emissions reductions associated with continuing to regulate those storage tanks containing significant amounts of ethylene oxide. The 1,000 ppmw threshold is also identical to the ''in ethylene oxide service'' criterion for applicability to the ethylene oxide-specific requirements for equipment leaks, which should also streamline applicability determinations for process equipment, piping, and storage tanks. Because of its reactivity, ethylene oxide is stored either as a pure component or in solution with other material in very low concentrations (*e.g.,* at impurity levels). We agree with commenters that emissions from tanks storing impurity levels of ethylene oxide are very low and do not result in additional risk. We agree that raising this threshold will reduce the cost of compliance for those facilities that may store and use a chemical that contains ethylene oxide at very low levels but for which emissions are negligible. We are also not providing additional constraints or clarifications on the determination of the threshold (*e.g.,* providing averaging times) for this revised threshold as we believe it is no longer needed and note that the EPCRA and supplier notifications will generally be the basis for applicability determinations.

We are not revising the threshold for process vents. First, we do not support the same threshold for process vents as tanks (1,000 ppmw), as some commenters suggest, because this value would essentially exempt all ethylene oxide-containing process vents that we have information on in the source category and would, therefore, not result in any reductions in emissions or risks. Other commenters have suggested a lower threshold of 20 ppmv ethylene oxide. We note that the process vent ethylene oxide concentrations measured in response to the CAA section 114 request ranged from 4 ppmv to 120 ppmv, and the quantifiable detection limit was below 0.5 ppmv. Therefore, we consider the proposed 1 ppmv threshold reasonable in terms of being measurable and quantifiable and also appropriate for the vent stream characteristics we intended to regulate that resulted in risk reductions. We also are not revising the 5 lb/yr mass threshold for the process vents, as the commenters did not suggest an alternative value to the mass-based threshold, although we agree that it was our intent that it be applied on an MCPU-by-MCPU basis. We also are not finalizing suggested provisions for sampling sites to remain consistent with the current MON requirements regarding the determination of uncontrolled emissions as they apply to both batch and continuous process vents. The location for determining the concentration and mass threshold is already provided in the MON, which includes ''the point of discharge to the atmosphere or the point of entry into a control device'' as the location of the process vent. For this reason, we are also revising the definition of ''in ethylene oxide service'' to remove the phrase ''anywhere in the process'' to clarify, as we have adequately specified the point at which the process vent characteristics should be evaluated. Finally, we have also removed the phrase ''undiluted'' from the mass-based criteria in the definition of in ethylene oxide service as we agree it does not apply to a mass-based threshold.

Comment: One commenter contended that the preamble discussion and proposed language in the rule is unclear as to whether the existing 0.005 weight percent total organic HAP cut-off in 40 CFR 63.107(d) of the continuous process vent definition (as referenced by the MON's continuous process vent definition in 40 CFR 63.2550) and the 50 ppmv HAP and 200 lb/yr uncontrolled HAP emission cut-offs in the batch process vent definition in 40 CFR 63.2550 still apply relative to the definition of ''in ethylene oxide service'' for process vents. The commenter requested the EPA confirm that since there is not specific language in the rule eliminating these exemptions for continuous and batch process vents in ethylene oxide service, we assume that the exemptions could still potentially apply. The commenter explained their interpretation of the proposed rule is that before the ethylene oxide requirements for process vents apply, the gas stream or emission stream must first meet the ''continuous process vent'' or ''batch process vent'' definition in 40 CFR 63.2550.

Response: The commenter is incorrect in their interpretation. In the proposed and final rule, process vents in ethylene oxide service are defined separately, and the existing 0.005 weight percent total organic HAP cut-off in 40 CFR 63.107(d) of the continuous process vent definition (as referenced by the MON's continuous process vent definition in 40 CFR 63.2550) and the 50 ppmv HAP and 200 lb/yr uncontrolled HAP emission cut-offs in the batch process vent definition in 40 CFR 63.2550 do not apply to the definition of ''in ethylene oxide service'' for process vents. Nevertheless, we are clarifying the definitions of ''batch process vent'' and ''continuous process vent'' in the final rule to make clearer that these cut-offs

do not apply to process vents in ethylene oxide service. We note that process vents could contain HAP other than ethylene oxide, and, therefore, it is possible that a process vent could be both in ethylene oxide service and also considered a Group 1 or Group 2 process vent. Owners or operators should consider all definitions that may apply as well as all control requirements when evaluating applicability and compliance obligations.

Comment: In response to our request for comment on the co-proposed Control Options for equipment leaks in ethylene oxide service, some commenters supported requiring equipment leak Control Option 2 for equipment in ethylene oxide service because health risks are unacceptable. One commenter contended that the EPA allowing the residual risks from these two highest risk facilities to be above the EPA's acceptable cancer risk level of 100-in-a-million, after leak controls, would set an unsatisfactory precedent for future RTRs. The commenter suggested that the EPA consider this an iterative process with regards to leak controls and pursue the goal of further reducing risks below the 100-in-a-million cancer risk level. Other commenters requested that the EPA apply Control Option 2 to all facilities in ethylene oxide service.

Some commenters did not support either equipment leak Control Option 1 or 2 for equipment in ethylene oxide service, but if the EPA were to finalize one of the options, they would prefer Control Option 1 with modifications. One commenter contended that the risks from the two facilities are substantially overstated so neither option is necessary, but Control Option 1 would be sufficient to reduce risks. Some commenters opposed the use of leakless valves in Control Option 2 for ethylene oxide service because of safety concerns. The commenters contended that leakless valves are more likely to trap ethylene oxide in valve cavities, and stagnant ethylene oxide polymerizes, creating heat that can cause explosions. The commenters added that the EPA inadequately addressed these safety issues and cited no actual experience with such designs in ethylene oxide service.

Commenters contended that the EPA's cost analysis for leakless valves significantly underestimates costs. One commenter added that the EPA's estimate does not include costs for engineering analysis or installation of valves, which are typically 2 to 3 times the equipment cost. One commenter added that engineering costs could be significant as bellows valves are heavier than existing equipment and evaluation for additional piping supports would be required, and the larger size of these valves would likely require reconfiguration and refabricating process piping for required clearance. The commenter continued that replacing existing valves with leakless valves will require an extended process shutdown to clear and purge the process and then replace the valves and that the EPA provides no information on the time to do this or the cost to affected companies of lost production.

Response: We agree that Control Option 1 for equipment in ethylene oxide service would sufficiently reduce risks, and we are finalizing Control Option 1 in the final rule, except as discussed later in this section of the preamble, in lieu of prohibiting PRDs in ethylene oxide service from releasing directly to the atmosphere, we are clarifying in the final rule that these PRDs must comply with the pressure release management work practice standards proposed at 40 CFR 63.2480(e) and (f), and any release event from PRDs in ethylene oxide service is a deviation of the standard. During the comment period, commenters provided updated information on their facilities, including specific information regarding sources in their facility that are subject to the MON, emissions from each source, controls in use, and operating information. We updated the risk assessment for the two facilities that, at proposal, had a MIR greater than 100-in-1 million. As discussed previously in this section of the preamble, after application of the ethylene oxide-specific controls for process vents, storage tanks, and equipment leaks from co-proposed Control Option 1, we find that the revised risks are acceptable and that the final standards will achieve an ample margin of safety to protect human health.

We reviewed whether Control Option 2 would provide additional emission reductions but determined that Control Option 2 was not appropriate to apply to equipment in ethylene oxide service based on comments and information received on the proposed rule. First, we reviewed the comments and information provided by the commenters and agree that there are potential safety concerns with the use of leakless valves for ethylene oxide service. We agree that many leakless valve designs, such as bellows seal valves, have extended packing cylinders, which have more volume and areas where ethylene oxide can be trapped and polymerize, resulting in the valve stem to stop working and the potential for explosions. No information was provided by commenters or identified from our review of available data for other sources that indicated that leakless valves are being or have been used for ethylene oxide service. Because of the safety concerns and no evidence that leakless valves are successfully being used for ethylene oxide service at this time, the final rule does not require their use. The current MON rule already requires gas and light liquid valves to be monitored at a leak definition of 500 ppm, and we did not propose different leak definitions for valves as part of Control Option 1. Secondly, although leakless pumps have been used instead of light liquid pumps for processes in ethylene oxide service, new data obtained during the comment period from Lanxess indicated that this facility does not have pumps in light liquid service that would be subject to the leakless pump requirement. Therefore, a requirement to install leakless pumps for light liquid pumps would not result in any changes to the estimated risks. As a result of the comments and information received and the results of the revised Risk Assessment, we are finalizing Control Option 1 for equipment leaks.

Comment: Several commenters disagreed with the operating parameters we proposed to require be continuously monitored for scrubbers used to control emissions from process vents and storage tanks in ethylene oxide service. Several commenters noted that column pressure drop is a reliable measurement for scrubbers that can identify flooding conditions, but may not identify channeling conditions, when scrubber efficiency is depleted as gas flow ''channels'' around the liquid blowdown. One commenter contended that background documents in the rulemaking docket do not have any justification for requiring a maximum pressure drop as an operating parameter limit, but speculated that the EPA had proposed a maximum to address a decrease in removal efficiency due to plugging or fouling of the packed bed. Commenters stated that engineering design should be allowed for establishing the critical process parameters for monitoring. One commenter stated that setting the maximum operating limit as the average measured during the performance test is impracticable because the pressure drop during the performance test will be measured when the packing material is cleanest. The commenter added that over time the packing material may foul and pressure drop may increase, but not to an extent which causes decreased performance. The commenter continued that the pressure drop will increase as

either gas flow or liquid flow through the scrubber increases. The commenter added that the requirement to operate below a maximum pressure drop conflicts with the requirement to operate above a minimum liquid to gas ratio. The commenter concluded that if the EPA retains the requirement to operate below a maximum pressure drop in the final rule, facilities should be allowed to set the maximum pressure drop based on manufacturer's recommendations or an engineering evaluation, not the average pressure drop measured during the most recent performance test.

Additionally, several commenters contended that monitoring liquid feed pressure is redundant with monitoring liquid-to-gas ratio and should not be included in the final rule. Commenters contend that monitoring feed pressure is an indirect method to assess scrubber liquid supply, while monitoring the scrubber liquid-to-gas ratio requires direct measurement of the liquid inlet flow rate.

Response: The EPA is maintaining the requirement to monitor pressure drop across the scrubber and liquid feed pressure to the scrubber in the final rule. As commenters note, pressure drop across a scrubber is a valuable piece of information on the operation of the scrubber. It can indicate issues with flooding, plugging, channeling, and fouling of the control device. However, we do agree with commenters that it may be challenging to establish the maximum pressure drop at the same time as the minimum liquid-to-gas ratio is established. The liquid-to-gas ratio is the primary parameter of concern in a typical wet scrubber system because it ensures that there is enough liquid available to clean the gas flowing through the system. Therefore, while we are maintaining the requirement to monitor pressure drop across the scrubber, in the final rule, we are allowing a pressure drop range to be established based on the manufacturer's recommendation or engineering analysis.

We disagree with commenters that the liquid feed pressure is redundant to the liquid flow rate. While the liquid feed pressure should indicate that liquid is flowing in the system, liquid feed pressure is also important for determining that the liquid is being appropriately dispersed within the scrubbing system, which is not something that the liquid flow rate alone can indicate. We think that ensuring the dispersion of the liquid stream is especially critical in ethylene oxide control, in order to ensure that the ethylene oxide adsorbs into the liquid stream so that it can undergo the conversion reaction. However, we are also aware that increases in liquid feed pressure can also be caused by blockages in the nozzle, and as such, the minimum pressure could be met without the nozzle properly atomizing the liquid stream. While we continue to believe that this is an important operating parameter for ethylene oxide scrubbers, we believe that this parameter does not necessarily need to be based on the performance test, and that the manufacturer should be able to provide information on what pressure in the nozzle will ensure proper operation of the nozzle. Therefore, while we are maintaining the requirement to monitor liquid feed pressure, in the final rule, we are allowing a liquid feed pressure range to be established based on the manufacturer's recommendation or engineering analysis.

Comment: Commenters requested the EPA revise the requirement to demonstrate compliance with the operating parameter limits for scrubbers used to control emissions from process vents and storage tanks in ethylene oxide service from an instantaneous basis to a daily average basis. Commenters explained that a daily average is consistent with the currently applicable requirements of 40 CFR part 63, subpart SS. One commenter stated that an instantaneous compliance demonstration with a measured value will likely lead to operators unnecessarily adjusting operating parameters in response to brief excursions due to changing process conditions. Another commenter explained that automated controls which maintain flow rate, temperature, pH, and other variables are typically ''feedback'' based or ''closed loop control,'' and even the best tuned controllers have some amount of response time. The commenter added that instantaneous compliance demonstrations will invariably lead to operators manually attempting to adjust control system variables which will likely lead to overshoot and potentially decreased control efficiency and concluded that the EPA must allow some amount of averaging to account for the inherent response time of control systems and deadtime of process response.

One commenter added that a daily average aligns better with the process of establishing the parameter operating limits during a performance test, which typically consists of three 1-hour runs. Another commenter contended that the rule should at least allow for 3-hour averages and stated this would be more consistent with other 40 CFR part 63 MACT rules (such as the Hazardous Organic NESHAP (HON)) and with the process of establishing the parameter operating limits during a performance test (*i.e.,* testing typically consists of three 1-hour runs).

Response: The EPA is changing the continuous compliance requirements for the operating parameters, such that compliance with the operating parameter limits is determined on an hourly average basis instead of an instantaneous basis. We agree that instantaneous limits on operating parameters may cause some unintended consequences with control loops and that some degree of averaging is warranted.

While we acknowledge that compliance with other operating parameters for MON sources is based on a daily average, per the requirements in 40 CFR part 63, subpart SS, we do not agree that this averaging basis is appropriate for operating parameters on control devices used for ethylene oxide process vents and storage tanks. Control devices used for ethylene oxide emissions operate differently than other control devices and are required to achieve better control than other control devices. In order to achieve 99.9-percent control from these devices, it is important to ensure that the ethylene oxide control is continuously occurring. These control devices tend to be used on batch processes, where the ethylene oxide emissions may fluctuate greatly with different steps in the process. Longer averaging times could mask issues with achieving the required control efficiency during brief periods of higher ethylene oxide loading to the control device (*e.g.,* during tank loading events). In order to ensure continuous compliance with the control efficiency requirement, we are requiring compliance with the operating parameters be based on a 1-hour average in the final rule.

Comment: Commenters interpreted the proposed language at 40 CFR 63.2493(d)(4) to mean that (1) the discharge piping on PRDs in ethylene oxide service cannot be routed to the atmosphere and (2) any release event is an automatic violation of the MON rule. Commenters contended that the proposed rule seems to require that the PRD be directed to some form of emission control equipment, such as a flare. Commenters opposed requiring all PRDs in ethylene oxide service vent to a control device. Commenters contended the requirement would create safety concerns including the hydraulic limitations of the flare or other control device, backpressure limitations on the PRDs, and the incompatibility of

chemicals in vent streams in downstream controls. Commenters noted that ethylene oxide is a compound which contains oxygen and is highly reactive, extremely flammable, and can violently decompose with a significant release of heat in the absence of air, and ethylene oxide also tends to polymerize, which could result in plugging of the closed vent system or control device. The commenter concluded that existing closed vent systems and control devices require careful evaluation to determine if emissions from such events can be safely controlled.

A commenter stated that because they are of limited duration and number, such events would not lower cancer risks, which are based on long term exposures. The commenter pointed out that the EPA makes no mention of PRDs when discussing ethylene oxide risk drivers.

The commenter stated that the same technical limitations that apply to PRDs in general also apply to those in ethylene oxide service. Commenters supported requiring PRDs in ethylene oxide service to comply with the proposed PRD work practice at 40 CFR 63.2480(e). A commenter stated that other existing EPA regulations already require the owner/operator to minimize or eliminate the potential for such releases, such as the EPA regulations at 40 CFR part 302 and 40 CFR part 355 have a 10-pound reportable quantity for ethylene oxide if a release from any equipment occurs. The commenter added that if a release greater than 10 pounds occurs, then the owner/operator must report it to the National Response Center, the State Emergency Response Commission (typically a state environmental agency), and the Local Emergency Planning Committee when the owner/operator has knowledge of such a release.

A commenter added that a MON MCPU may not have a flare or may be located in an area of a larger site where there is not adequate land space for a flare.

A commenter added that if a new flare or other emission control equipment is required, design and installation of a flare system or other emission control equipment within 2 years of the final date of this rule is not practical. Commenters stated that typically, it takes 3 years to properly engineer the project, obtain capital authorization and funding, procure the equipment, and construct and start-up the equipment. Commenters noted that the EPA has not provided any background information in the preamble or in the rule docket that addresses costs or the feasibility of installing large flares or other air emission control equipment within the 2-year compliance period.

Response: We are revising the proposed requirement that PRDs in ethylene oxide service must not vent directly to the atmosphere. In lieu of prohibiting PRDs in ethylene oxide service from releasing directly to the atmosphere, we are clarifying in the final rule that these PRDs must comply with the pressure release management work practice standards proposed at 40 CFR 63.2480(e) and (f). We are also clarifying that any release event from PRDs in ethylene oxide service is a deviation of the standard. We are finalizing these requirements pursuant to CAA section 112(f)(2), on the basis for risks being unacceptable. Where we find risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. Because emissions of ethylene oxide from this source category result in unacceptable risks, we proposed and are finalizing requirements that would reduce risks to an acceptable level, including provisions that would make all PRD releases of ethylene oxide directly to the atmosphere a violation of the standard. We believe that there are very few PRDs in ethylene oxide service that vent to the atmosphere. Note that the proposed rule does not specify that PRDs must be controlled with flares; in fact, the detailed information we have indicate that most of these emission sources are controlled using scrubbers. Further, we reviewed emission release reports from the National Response Center for the 5-year period beginning in 2015 through 2019 and identified only one reported release of ethylene oxide from an ethylene oxide production facility which is not part of the Miscellaneous Organic Chemical Manufacturing source category. Also, during the public comment period, commenters did not submit any specific information on the existence of, or lack of, ethylene oxide releases from PRDs in the Miscellaneous Organic Chemical Manufacturing source category. Therefore, we maintain that controlling PRDs in ethylene oxide service is possible, and in fact represents the majority of industry's practice in this source category.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive benchmark on MIR of approximately 1-in-10 thousand'' (84 FR 54278, October 9, 2019; see also 54 FR 38045, September 9, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum cancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, multipathway risks, and the risk estimation uncertainties.

Since proposal, our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects have not changed. However, after proposal, commenters provided updated information on their facilities, including specific information regarding sources in their facility that are subject to the MON, emissions from each emissions source, controls in use, and operating information. We updated the risk assessment for the two facilities that, at proposal, had a MIR greater than 100-in-1 million. The revised risk assessment (see document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking) shows that, after application of controls finalized in this rulemaking, the MIR for the source category is 200-in-1 million.

As discussed in section IV.A.3.b of this preamble, the 100-in-1 million cancer risk is not a bright line indicating that risk is ''acceptable''; rather, we consider this health metric in conjunction with a variety of health factors and their associated uncertainties to determine whether the risk is acceptable. We considered the number of people exposed to risks greater than 100-in-1 million (107 people, or 0.0001 percent of the population living near a facility in the source category), the cancer incidence (0.09), and the number of people exposed to cancer risk levels greater than 1-in-1 million (1,400,000 people, or 2 percent of the population living near a facility in the source category), which are consistent with other rules where risks above 100-in-1 million were found to be acceptable (see section IV.A.3.b of this preamble for more details). We also considered that no safe controls were identified to further reduce risks. Therefore, considering the uncertainties inherent in all risk assessments as discussed in the preamble to the proposed rule (*i.e.,* the emissions dataset, dispersion modeling, exposure

estimates, and dose-response relationships) (see 84 FR 69219) and the EPA's use of the 2016 IRIS URE for ethylene oxide (which is developed to be health protective), and additional considerations discussed here and in more detail in section IV.A.3.b of this preamble, after application of the ethylene oxide-specific controls for process vents, storage tanks, and equipment leaks from co-proposed Control Option 1, we find that the risks are acceptable and that the final standards will achieve an ample margin of safety to protect human health.

B. Technology Review for the Miscellaneous Organic Chemical Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Miscellaneous Organic Chemical Manufacturing source category?

Based on our technology review for the Miscellaneous Organic Chemical Manufacturing source category, we proposed under CAA section 112(d)(6) changes to the standards for equipment leaks and heat exchange systems, and we proposed no changed under CAA section 112(d)(6) for process vents, storage tanks, transfer racks, and wastewater streams. We provide a summary of our findings, as proposed, in this section.

a. Equipment Leaks

In our technology review for the Miscellaneous Organic Chemical Manufacturing source category, we identified developments in LDAR practices and processes for equipment leaks (excluding equipment in ethylene service). We identified four options for lowering the leak definition for certain process and component types and requiring periodic monitoring, and the options varied by leak definition level, process type (*i.e.,* batch process v. continuous process), component type, and monitoring frequency. Refer to section IV.D.1 of the proposal preamble (84 FR 69182, December 17, 2019) for a summary of the four options. Based on our evaluation of the costs and emission reductions of each of the four options, we determined that the most cost-effective strategy was to lower the leak definition for pumps in light liquid service (in an MCPU that has no continuous process vents and is part of an existing source) from 10,000 ppmv to 1,000 ppmv with monthly monitoring and initial monitoring within 30 days after initial startup of the equipment, which we proposed pursuant to CAA section 112(d)(6) to further reduce HAP emissions from equipment leaks for MON equipment not in ethylene service.

For a detailed discussion of the EPA's findings, refer to the memorandum, *Clean Air Act Section 112(d)(6) Technology Review for Equipment Leaks Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0003).

b. Heat Exchange Systems

In our technology review for the Miscellaneous Organic Chemical Manufacturing source category, we identified one development in practices and processes for heat exchange systems, the use of the Modified El Paso Method [17] for monitoring for leaks from heat exchange systems. We determined that this method is more effective in identifying leaks and measures a larger number of compounds than the methods previously required in the MON. After evaluating state and Federal regulations requiring the Modified El Paso Method, as well as emission data collected for the Ethylene Production RTR (refer to section II.D of the proposal preamble (84 FR 69182, December 17, 2019) and the Ethylene Production RTR rulemaking docket, Docket ID No. EPA–HQ–OAR–2017–0357), we proposed pursuant to CAA section 112(d)(6) to require use of the Modified El Paso Method with a leak definition of 6.2 ppmv of total strippable hydrocarbon concentration (as methane) in the stripping gas to further reduce HAP emissions from both new and existing heat exchange systems, as well as to disallow delay of repair of leaks if the measured concentration meets or exceeds 62 ppmv. Based on an evaluation of incremental HAP cost effectiveness to increase the monitoring frequency, we proposed no changes to the monitoring frequency previously required under the MON for monitoring for leaks from heat exchange systems, which continues to be monthly monitoring in the first 6 months following startup of a source and quarterly monitoring thereafter. We also proposed to require re-monitoring at the monitoring location where a leak is identified to ensure that any leaks found are fixed. Further, we proposed that none of these proposed requirements for heat exchange systems apply to heat exchange systems that have a maximum cooling water flow rate of 10 gpm or less. Refer to section IV.D.2 of the proposal preamble (84 FR 69182, December 17, 2019) for a summary of our rationale for selecting the proposed leak method, leak definition, and limitation on delay of repairs, as well as our rationale for retaining the previous monitoring schedule.

For a detailed discussion of the EPA's findings, refer to the memorandum, *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0007).

c. Process Vents, Storage Tanks, Transfer Racks, and Wastewater Streams

In our technology review of process vents, storage tanks, transfer racks, and wastewater streams for the Miscellaneous Organic Chemical Manufacturing source category, we identified no cost-effective developments in practices, processes, or control technologies for these emissions sources that would achieve a greater HAP emission reduction beyond the emission reduction already required by MON. Therefore, we proposed no revisions to the MON pursuant to CAA section 112(d)(6) for process vents, storage tanks, transfer racks, and wastewater streams. For a detailed discussion of the EPA's findings, refer to the memorandum, *Clean Air Act Section 112(d)(6) Technology Review for Process Vents, Wastewater, Transfer Racks, and Storage Tanks Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0008). This analysis is also described in detail in section IV.B of the preamble to the proposal preamble (84 FR 69182, December 17, 2019).

2. How did the technology review change for the Miscellaneous Organic Chemical Manufacturing source category?

We are finalizing the results of the technology review for the Miscellaneous Organic Chemical Manufacturing source category as proposed (84 FR 69182, December 17, 2019), with the following exceptions.

[17] The Modified El Paso Method uses a dynamic or flow-through system for air stripping a sample of the water and analyzing the resultant off-gases for volatile organic compounds (VOC) using a common flame ionization detector (FID) analyzer. The method is described in detail in Appendix P of the TCEQ's Sampling Procedures Manual: *The Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound (VOC) Emissions from Water Sources.* Appendix P is included in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0024).

For equipment leaks not in ethylene oxide service, based on comments received on the proposal, we are clarifying in the final rule that the initial monitoring of equipment is only required if the new or replaced equipment is subject to Table 6 to 40 CFR part 63, subpart FFFF, and is also subject to periodic monitoring with EPA Method 21 of appendix A–7 to 40 CFR part 60 and that the initial monitoring does not apply to equipment classified as unsafe-to-monitor or difficult-to-monitor equipment.

For heat exchange systems, we are taking final action on the proposed requirement to monitor leaks from heat exchange systems using the Modified El Paso Method consistent with the December 17, 2019, RTR proposal. However, based on comments received on the proposed rulemaking, we are also making some technical clarifications to allow compliance with the Modified El Paso Method using an alternative mass-based leak action level of total strippable hydrocarbon equal to or greater than 0.18 kilograms per hour (instead of the proposed concentration-based leak action level) for small heat exchange systems with a recirculation rate of 10,000 gpm or less.

3. What key comments did we receive on the technology review, and what are our responses?

This section provides comment and responses for the key comments received regarding our proposed revisions for equipment leaks; heat exchange systems; and process vents, transfer racks, storage tanks, and wastewater streams. Other comment summaries and the EPA's responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed revisions, can be found in the document *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

For equipment leaks not in ethylene oxide service, we received comments on potential issues and problems associated with the proposed requirements for pumps in light liquid service (in an MCPU that has no continuous process vents and is part of an existing source) to meet a leak definition of 1,000 ppmv and requiring facilities to initially monitor for equipment leaks within 30 days after initial startup of the equipment. See section IV.B.3.a of this preamble for further details.

For heat exchange systems, the EPA received additional information from commenters on costs necessary for control of these sources as well as comments on a number of technical clarifications and allowance of compliance with an alternative mass-based leak action level should the EPA finalize the requirements for heat exchange systems. See section IV.B.3.b of this preamble for further details.

For process vents, transfer racks, equipment leaks, and wastewater streams, the comments were supportive of the determination that no cost-effective developments from the technology review were found. See section IV.B.3.c of this preamble for further details.

a. Equipment Leaks

Comment: A commenter requested the EPA not finalize the lowering of the leak definition for batch light liquid pumps from 10,000 ppm to 1,000 ppm because it inadvertently removes existing exemptions for all pumps. The commenter contended that instead of simply nullifying 40 CFR 63.2480(b)(5), which sets the leak definition to 10,000 ppm for batch pumps, the language in 40 CFR 63.2480(b)(6) appears to apply to all pumps, not just those for batch processes. The commenter added that as a result, the leak definitions for pumps in specific service (*i.e.,* polymerizing polymers and food/medical service) and the 2,000 ppm repair threshold in subparts H and UU will be overwritten. The commenter contended that the EPA has provided no analysis or justification for such a change. The commenter added that if the revision is intended to apply only to batch pumps, this results in continuation of different standards for batch and continuous pumps. The commenter suggested that to clarify the requirements and streamline compliance the EPA should apply the same standards to all pumps in light liquid service.

Response: We agree with the commenter that the proposed requirement of a leak definition of 1,000 ppm for light liquid pumps at both batch and continuous processes directly in the MON rule inadvertently overrode facilities complying with the equipment leak requirements in subparts H and UU as the MON references both rules for leak definitions. The intention of the proposed requirement was to make the light liquid pump requirements for batch processes the same as the existing requirements for continuous processes and streamline the requirements by codifying them in the MON rule. The intention was not to remove the existing exemptions or repair requirements. We have revised the final rule to require light liquid pumps in batch and continuous processes that are not in ethylene oxide service to comply with the requirements in 40 CFR part 63, subpart H or UU, or 40 CFR part 65, subpart F, which is a leak definition of 1,000 ppmv, by removing the exemption for light liquid pump monitoring in 40 CFR 63.2480(b)(5) and 40 CFR 63.2480(c)(5) and removing the proposed leak definition in the MON.

Comment: Some commenters requested the EPA not finalize the proposed requirements at 40 CFR 63.2480(b)(7) and (c)(11) that specify initially monitoring leaks 30 days after initial startup of the equipment. The commenters contended this requirement adds a significant burden that the EPA did not consider, nor has the EPA provided any justification as to whether this requirement would provide any emissions reductions.

One commenter contended that 40 CFR 63.2480(b)(7) and (c)(11) specify that ''each piece of equipment'' must be monitored initially for leaks within 30 days after initial startup of the equipment and that the term ''Equipment'' is already defined in the MON at 40 CFR 63.2550. The commenter contended that this could be interpreted to require this 30-day monitoring requirement to apply to every single piece of equipment within the scope of the ''Equipment'' definition regardless of monitoring exemptions or the fact that some component types do not require routine monitoring. The commenter stated that equipment excluded from monitoring under the MON (*e.g.,* equipment routed to control, fuel gas or a process; equipment in heavy liquid service; instrumentation systems; open-ended lines and valves; and connectors) should be excluded from this new requirement. The commenter also contended that pumps and agitators are already checked weekly and monthly and thus should be excluded from this new requirement and that, for clarity and simplicity, it would be simplest to limit these new requirements to gas and light liquid valves. The commenter also requested that the EPA clarify that ''replacement'' does not include reinstalling an item of equipment that has been removed for inspection or repair. The commenter provided an example of PRDs that are typically removed for bench testing and then replaced. The commenter continued that since the bench test confirms the PRD does not open until the set pressure is reached, there is no need to test it outside of the normal periodic schedule. The commenter also identified repaired equipment as already being required to re-monitor within 15 days and thus should also be

excluded from the 30-day requirement. Another commenter recommended that this initial monitoring requirement should also apply only to equipment that is subject to periodic monitoring with EPA Method 21 of appendix A–7 to 40 CFR part 60.

Some commenters stated that the proposed requirement would require significant training of maintenance and operations staff and development and implementation of tracking systems to ensure no equipment component is replaced or added without conducting the 30-day monitoring. Commenters stated that this will place a significant burden and cost to an MCPU and that the EPA did not consider the burden associated with tagging, updating the LDAR program, and managing the component-by-component leak schedule this proposed requirement will impose, especially for equipment that is added or replaced frequently within an MCPU.

Commenters contended some MON processes restrict additional personnel, such as LDAR personnel, in their operating areas for safety reasons; and some equipment is never safe to monitor while in service. The commenters added that safety restrictions may be in place for a period of time, which then reduces the number of days in the 30-day period for the initial monitoring. One commenter concluded that a 30-day period is not long enough to organize the initial monitoring for these components or even components in less restricted areas.

One commenter stated that the compliance date section in 40 CFR 63.2445(g)(3) does not mention when the 30-day requirement in 40 CFR 63.2480(b)(7) and (c)(11) becomes effective, so it appears that the language might be effective the date the final rule is published. The commenter recommended that the requirement in 40 CFR 63.2480(b)(7) and (c)(11) to initially monitor each piece of equipment for leaks within 30 days after initial startup of equipment should be amended to reference the language in 40 CFR 63.162(g) of HON subpart H and 40 CFR 65.3(d) of the Consolidated Federal Air Rule to determine the first monitoring period depending on how many days are left in the week, weeks remaining in the month, months remaining in the quarter, and quarters remaining in the year. Two commenters stated that if the EPA promulgates these requirements, the proposed applicability date should be changed from December 17, 2019, to 3 years after the date of publication of the final rule. One commenter stated that if the EPA promulgates these requirements, more time is needed, such as 3 months from the time components initially are in organic HAP service. The commenter contended that the EPA cannot impose requirements retroactively and that time is needed to develop the infrastructure to address this requirement.

One commenter contended that this change is presented as a ''clarification'' in the preamble discussion, but no such requirement was part of the negotiated rulemaking [18] that established the part 63 LDAR program, nor is such a requirement suggested in the existing language as shown by the EPA's need to propose new language to this rule to impose this requirement. The commenter claimed that this is a new requirement, not a clarification. The commenter added that as such, it must be justified under CAA section 112(d)(6). Commenters contended that nothing is presented in the MON record to show there is a problem with current (generally quarterly) periodic monitoring as specified in the existing 40 CFR part 63, subpart H or UU, or 40 CFR part 65, subpart F. One commenter said that the EPA appears to have recognized the challenges to implementing initial monitoring requirements 30 days after initial startup of equipment and cited the HON as it requires only new sources to initially monitor only valves in gas/vapor service and light liquid service quarterly. The commenter presumed that this provision was added to the HON for new sources because of the results of the MACT determination under the HON. The commenter concluded that the EPA had not conducted a MACT determination for this proposed provision under the MON, nor has it completed a cost-benefit or risk analysis necessary to add this requirement under this technology or risk review.

One commenter contended that by claiming this new requirement is a ''clarification'' it could mistakenly be construed as applying to all part 63 and 65 LDAR programs. The commenter stated that proposing this change in the MON RTR rulemaking does not provide adequate notice and an opportunity for comment to most of the sources potentially impacted. The commenter recommended that the EPA should clarify that this is a new requirement and is only applicable to sources subject to the MON and that it is not a clarification of existing requirements in 40 CFR part 63, subpart H or UU, or in 40 CFR part 65, subpart F.

Response: The EPA did not intend for the requirement to initially monitor components 30 days after initial startup of the equipment to apply as broadly as the commenters have interpreted. We intended for the requirement to only apply to new or replaced equipment regulated under the MON that must be periodically monitored with EPA Method 21. Similar requirements were promulgated in 40 CFR part 60, subparts VV and VVa. We agree with the commenters that the requirement to monitor equipment within 30 days of startup is not appropriate for equipment that are classified as unsafe-to-monitor or difficult-to-monitor due to their locations and safety concerns.

In the final rule, we are clarifying at 40 CFR 63.2480(b)(7) and (c)(11) that monitoring leaks within 30 days after initial startup applies only to new or replaced equipment that is subject to Table 6 to 40 CFR part 63, subpart FFFF, and is also subject to periodic monitoring with the EPA Method 21 of appendix A–7 to 40 CFR part 60. We are also clarifying that the requirement does not apply to equipment classified as unsafe-to-monitor or difficult-to-monitor equipment. Following the initial monitoring, the equipment may follow the periodic monitoring program applicable to each affected process unit. We are not changing the compliance date for this requirement in the final rule, and the requirement will be effective the date the final rule is published in the **Federal Register**. This requirement only applies to new and replaced components, and as such, we expect facilities are able to appropriately plan ahead for installation of new components.

We disagree with commenters that a 112(d)(6) review is needed for this requirement. The requirement to conduct initial monitoring of equipment for leaks within 30 days of startup is a clarification to the compliance provisions of an existing work practice, not a new work practice. As discussed earlier, a similar change was made for 40 CFR part 60, subpart VV. As we stated in that rulemaking (72 FR 64862), the change is a clarification of the initial monitoring requirements. The clarification is intended to provide certainty to owners or operators on the timeframe in which this compliance activity must be conducted.

b. Heat Exchange Systems

Comment: We received comments in support of and against the proposal to require use of the Modified El Paso Method for detecting and repairing leaks in heat exchange systems.

One commenter supported the use of the Modified El Paso Method, and stated that in the Ethylene Production

[18] Commenter provided the following reference: 57 FR 62617–62619 (December 31, 1992).

rulemaking, the EPA found that at least 20 heat exchange systems (at eight facilities) are already required by TCEQ's highly reactive volatile organic compounds (HRVOC) rule to conduct continuous Modified El Paso Method monitoring.

Some commenters opposed the proposed control requirements for heat exchange systems, stating the requirements were not cost effective when considering the actual costs to repair leaks. Some commenters said that the costs provided in Table 3 of the memorandum, *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category for the Final Rule,* significantly underestimate the true cost associated with leak repair at MON facilities. The commenters contended that the EPA has not taken into account that after identifying a leak, maintenance and operations personnel must develop a strategy and schedule to remove the leaking exchanger from service to conduct the repair. The commenter explained that this activity involves identifying and selecting options for bypassing the process stream from the leaking system, determining the amount of production turndown necessary while the exchanger is out of service, identifying and selecting the appropriate contract personnel, and scheduling the work so that it does not conflict with any other planned maintenance. The commenters said these steps alone require approximately 128 personnel hours. In addition to these costs, the commenters said that the EPA did not include costs for bypassing the leaking system to avoid a total shutdown, which may include renting and plumbing temporary heat exchangers. The commenters also said that the EPA did not include costs for the rental and installation of cranes and scaffolding for accessing the heat exchanger for repairs or costs for specialized contracted maintenance support to de-head the exchanger and perform the repair. The commenters contended that repair costs range from $200,000 to $400,000 per event, not considering lost profit due to turndown or shutdown of the production unit. Factoring in these additional costs and using the EPA's calculated HAP emissions reductions of 31 tons per year, the commenters said the revised cost effectiveness becomes $161,930 per ton of HAP. The commenters cited the NESHAP final RTR for Friction Materials Manufacturing Facilities (83 FR 19511) where the EPA found a $3,700 per ton cost for a permanent total enclosure not cost effective, and the NESHAP proposed RTR for the Petroleum Refinery Sector (79 FR 36916) where the EPA found a $14,100 per ton cost for lowering leak definitions not cost effective. The commenters stated that the EPA acknowledges in the preamble that emissions from heat exchange systems have no discernable impact on cancer risk for the modeled facilities and that additional controls for heat exchange systems are not necessary to provide an ample margin of safety.

One commenter requested that the EPA reconsider the cost information submitted on heat exchanger leak repairs in the context of MON, independent of the prior decision made for the Ethylene Production RTR. The commenter said that the EPA's response to their similar comment for the Ethylene Production RTR, that heat exchange systems for ethylene production facilities were not cost effective, was not persuasive. The commenter said that the EPA must consider the entire cost of a heat exchanger repair for the additional/incremental repairs that will be required as a result of lower effective leak definitions and restrictions to the delay of repair provisions; for example, if the current rule requires 4 leaks to be repaired, and the revised rule requires 5 leaks to be repaired, the incremental cost is the entire repair cost for the 5th repair, not a subset of the repair costs, because the current rule would not require the 5th repair at all. In addition, the commenter said they provided a detailed account of several components of repair costs and the range of typical repair costs, yet the EPA did not consider this information in the final rule for the Ethylene Production RTR (signed on March 12, 2020). The commenter also objected to the EPA's response, to similar comments in the pre-publication of the final rule for the Ethylene Production RTR, that the ACC did not provide additional information for the agency to determine the amount of time additional leaks would have to be fixed under the revised heat exchange system standards. The commenter contended that EPA already had sufficient data. The commenter said the EPA based the leak distribution analysis in the technology review memorandum for heat exchange systems at ethylene production facilities on continuous monitoring data from 13 heat exchange systems at six facilities, and the EPA indicated that no leaks in the data were above the current rule threshold; thus, all leaks at the average leak distribution chosen for analysis that were above the new leak detection threshold would be considered ''incremental repairs.''

One commenter contended that requiring the Modified El Paso method is not cost effective in all cases. The commenter stated that in certain cases, where soluble type HAP or VOC are the dominant organic species on the process side of the heat exchanger, the current leak detection method (*i.e.,* cooling water sampling to detect leaks) is ''adequate,'' and, therefore, the costs to change to using the El Paso method are ''not justified.'' The commenter explained that mandated conversion of their 56 heat exchanger systems (HES) to the Modified El Paso method would require installation of tubing and taps to set up sampling stations for the El Paso apparatus. The commenter added that where there is not room or access close by the HES, remote stations would have to be established. In order to take the measurements, the commenter stated that an LDAR Method 21 technician must accompany operators to the sampling locations and move the El Paso apparatus from location to location; otherwise, multiple El Paso sampling devices would have to be installed. The commenter contended that the costs associated with the proposed change are not justified when the current method is adequate to detect leaks.

Response: The EPA is finalizing the proposed technology review revision under CAA section 112(d)(6) for heat exchange systems to use the Modified El Paso Method, with some minor technical clarifications that are discussed elsewhere in this section of this preamble and in the *Summary of Public Comments and Responses for the Risk and Technology Review for the Miscellaneous Organic Chemical Manufacturing Source Category,* available in the docket for this rulemaking. However, we disagree with commenters who said these proposed revisions are not cost effective. We believe that the developments we identified for heat exchange systems at MON sources are cost effective. We note that the existing MACT standards that were finalized in 2003 contain LDAR provisions; therefore, many of the costs mentioned by commenters (*i.e.,* planning, bypassing, various equipment rental/purchase costs, and costs for scaffolding) are associated with repair costs that would have already been incurred under the existing MACT standards. Also, many of the items associated with cost that are listed by the commenters are not required by the rule, and the commenters did not provide sufficient information

demonstrating why these costs represent an average heat exchange system at a MCPU. For example, facilities may have additional heat exchange system capacity available to them at their facility and may opt to use this capacity to repair the leak, at no additional expense, yet this was not considered by commenters.

Furthermore, because commenters did not provide information sufficient for us to evaluate the percentage of time additional leaks would have to be fixed under the proposed heat exchange system standards compared to the original MACT standards, we continue to believe that the majority, if not all, of the repair costs cited by commenters would have been accounted for and incurred as a result of the original MACT standards and that simply plugging a leaking heat exchanger would more likely represent the average cost additionally incurred by MON sources as a result of this technology review development. In addition, we stated in the proposed rule that we considered a heat exchanger that was leaking to the extent that it needed to be replaced to be effectively at the end of its useful life, so the cost of replacing the heat exchanger would be an operational cost that would be incurred by the facility as a result of routine maintenance and equipment replacement and not attributable to the work practice standard.

Thus, given all of this information, we continue to believe that the only costs that would be additionally incurred by the proposed heat exchange system standards would be costs associated with the difference between doing leak sampling using water sampling methods and leak sampling using the Modified El Paso Method as well as with costs associated with combined operator and maintenance labor to find and repair a leak by plugging it. We also maintain that for almost all MON facilities,[19] the use of the Modified El Paso method is much more sensitive in terms of being able to identify leaks of organic HAP compared to water sampling methods, and monitoring for a single surrogate parameter of organic HAP such as total strippable hydrocarbon can be easily accomplished with a single measurement using a common flame ionization detector (FID).

We note that, based on data collected for ethylene sources, we anticipate that the subsequent leak distribution would reasonably represent implementation of the Modified El Paso Method because it is the average leak distribution of 13 heat exchange systems at 6 ethylene facilities using this method. However, given that the initial leak distribution is based on a heat exchange system employing continuous Modified El Paso monitoring, it is likely that emission reduction estimates are understated given that the average MON facility does not have such readily available information on leaks and would only acquire such information on a quarterly basis using considerably higher leak sensitive test methods. In other words, and as described in more detail in our technology review memorandum for heat exchange systems (see *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which is available in the docket for this rulemaking), the initial leak frequency distribution would likely show considerably higher percentages of larger leaks due to the sensitivity of the current water sampling method requirements in the rule and due to the fact that the dataset was developed from facilities employing continuous monitoring as opposed to less frequent (*e.g.,* quarterly or monthly) monitoring. However, this was the best available data available to the agency, and so we used these conservative estimates. Based on our analysis, we find that the revised standards we proposed for heat exchange systems are cost effective at $8,530/ton of HAP without consideration of product recovery and the requirement has the potential to lead to a cost savings with product recovery. Therefore, we are finalizing the revisions for heat exchange systems that we proposed under the technology review with some minor technical clarifications that are discussed elsewhere in this document.

We also note, with respect to other rules where we have determined control options to not be cost effective at varying levels of cost effectiveness, that other compelling factors in those rulemaking records likely led the EPA to those determinations and that each rulemaking record is unique and should be judged based on its own merits. With respect to the two proposed rules commenters cite (*i.e.,* friction materials RTR and petroleum refinery RTR) where the EPA determined certain controls to not be cost effective, the EPA considers a number of rule-specific factors when determining what is, and what is not, cost effective. Regardless, and as stated above, we believe that the developments we identified for heat exchange systems at MON sources are cost effective, and we are finalizing these revisions under our CAA section 112(d)(6) authority.

Comment: Two commenters recommended the EPA revise the heat exchange system requirements to include an alternative mass-based leak definition because it would reduce the overall costs of the final rule. The commenters argued that by only defining a leak on a concentration basis, smaller facilities with lower heat exchange system recirculation rates would be forced to identify and fix leaks with a much lower potential HAP emissions rate than facilities with larger recirculation systems. The commenters provided the EPA with survey results showing that 69 heat exchange systems subject to the MON rule have recirculation flowrates between 200 gpm and 80,000 gpm, except for four systems that have a flowrate greater than 80,000 gpm and that the average cooling water flow rate is 43,500 gpm. Based on this information, the commenters suggested the EPA establish an alternative leak action level of 1.6 pounds per hour of total strippable hydrocarbon and a delay of repair action level of 16 pounds per hour of total strippable hydrocarbon for systems with a recirculation flowrate less than or equal to 40,000 gpm. Another commenter said that the EPA must reduce the leak definition and aim to achieve zero leaks. The commenter also supported the use of the Modified El Paso Method, pointing out that in the Ethylene Production RTR, the EPA found that at least 20 heat exchange systems (at eight facilities) are already required by TCEQ's HRVOC rule to conduct continuous Modified El Paso Method monitoring.

Response: We agree with commenters that an alternative mass-based leak action level is warranted (in lieu of a concentration-based leak action level) and that, by not finalizing such an alternative, smaller heat exchange systems with low recirculation rates would be disproportionally affected and forced to repair leaks with a much lower potential HAP emissions rate than facilities with larger recirculation rate systems. As commenters allude to, the goal of this alternative is to avoid

[19] We are aware of only one MON facility where it is possible that the only HAP that has potential to be present in a heat exchange system is methanol and/or ethylene glycol. In this specific case, the Modified El Paso method may not be as sensitive as water sampling methods; and the owners or operators of this facility could submit more detailed information regarding their specific situation to the EPA and request an alternative test method or an alternative monitoring method pursuant to 40 CFR 63.7(f) and 40 CFR 63.8(f), respectively. Under 40 CFR 63.7(f) and 40 CFR 63.8(f) (in subpart A—General Provisions), a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

disproportionally impacting small heat exchange systems with low emissions potential. To that end and given that this is a technology review under CAA section 112(d)(6), consideration of where it is cost effective to repair a leaking heat exchange system is a consideration for this alternative mass-based leak action level. In the technology review memorandum, *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* available in the docket for this rulemaking, we determined that the nationwide impacts for HAP cost effectiveness (without consideration of product recovery) at $8,530/ton of HAP would be the HAP cost effectiveness for an average heat exchange system in the source category that has a recirculation rate of approximately 14,000 gpm. We also generally consider technology review developments to be near the upper end of acceptable cost effectiveness for organic HAP if the cost effectiveness is approximately $10,000/ton (or approximately 1.2 times higher than the cost effectiveness estimated for the average heat exchange system at MON sources). Since the recirculation rate directly correlates to mass emissions potential at the same leak concentration, the mass emissions for a heat exchange system with recirculation rate of 10,000 gpm or less (rounded to one significant figure) would be at least 1.2 times smaller compared to a 14,000 gpm recirculation rate system, and the annual costs to find and repair leaks would not change. As such, we determined that heat exchange systems with a recirculation rate of 10,000 gpm or less would be less cost effective to monitor and repair because the HAP cost effectiveness would be approximately $10,000/ton of HAP or more. Therefore, to alleviate the concern about disproportionally impacting small heat exchange systems with low HAP emissions potential, and to ensure our technology review developments are cost effective for all heat exchange systems in the source category, we are finalizing an alternative total hydrocarbon mass-based emissions rate leak action level (as methane) of 0.18 kilograms per hour (0.4 pounds per hour) for heat exchange systems in the Miscellaneous Organic Chemical Manufacturing source category that have a recirculation rate of 10,000 gpm or less. We also agree that for consistency, and to not disproportionately impact small heat exchange systems, an alternative mass-based leak action level of 1.8 kilograms per hour (4.0 pounds per hour) for delay of repair for heat exchange systems with a recirculation rate of 10,000 gpm or less is warranted.

c. Process Vents, Storage Tanks, Transfer Racks, and Wastewater Streams

Comment: Commenters supported the EPA's conclusion under the technology review that there are no cost-effective technology developments for process vents, storage tanks, transfer racks, and wastewater streams.

Response: We acknowledge the commenters' support for the EPA's technology review conclusions.

4. What is the rationale for our final approach for the technology review?

Our technology review focused on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MON standards were originally promulgated on November 10, 2003 (68 FR 63852), and further amended on July 1, 2005 (70 FR 38562), and July 14, 2006 (71 FR 40316). Specifically, we focused our technology review on all existing MACT standards for the various emission sources in the Miscellaneous Organic Chemical Manufacturing source category, including, storage vessels, process vents, transfer racks, equipment leaks, wastewater streams, and heat exchange systems. In the proposal, we identified cost-effective developments only for equipment leaks and heat exchange systems, and we proposed to revise the standards for these two emissions sources under the technology review. We did not identify developments in practices, processes, or control technologies for process vents, transfer racks, storage tanks, and wastewater streams. Further information regarding the technology review can be found in the proposed rule (84 FR 69182, December 17, 2019) and in the supporting materials in the rulemaking docket at Docket ID No. EPA–HQ–OAR–2017–0357.

During the public comment period, we received several comments on our proposed determinations for the technology review. The comments and our specific responses and rationale for our final decisions can be found in section IV.B.3 of this preamble and in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking. No information presented by commenters has led us to change our proposed determination under CAA section 112(d)(6) for process vents, transfer racks, storage tanks, and wastewater streams, and we are finalizing our determination that no changes to these standards are warranted. However, substantive information was submitted by commenters on proposed revisions for equipment leaks. Based on these comments, we are finalizing revisions for equipment leaks and making some technical clarifications to clarify that the initial monitoring of equipment is only required if the new or replaced equipment is subject to Table 6 to 40 CFR part 63, subpart FFFF, and is also subject to periodic monitoring with Method 21 of appendix A–7 to 40 CFR part 60 and that the initial monitoring does not apply to equipment classified as unsafe-to-monitor or difficult-to-monitor equipment. In addition, substantive information was also submitted by commenters on proposed revisions for heat exchange systems, and based on this information, we are finalizing revisions to require the Modified El Paso Method for heat exchange systems. We are also making some technical clarifications to allow compliance with the Modified El Paso Method using an alternative mass-based leak action level instead of a concentration-based leak action level for small heat exchange systems with a recirculation rate of 10,000 gpm or less.

C. Amendments Pursuant to CAA Section 112(d)(2) and (3) and 112(h) for the Miscellaneous Organic Chemical Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(d)(2) and (3) and 112(h) for The Miscellaneous Organic Chemical Manufacturing source category?

Under CAA sections 112(d)(2) and (3) we proposed to amend the operating and monitoring requirements for a subset of flares in the Miscellaneous Organic Chemical Manufacturing source category. We proposed that the subset of flares include flares in the Miscellaneous Organic Chemical Manufacturing source category that either (1) control ethylene oxide emissions, (2) control emissions from processes that produce olefins, or (3) control emissions from processes that produce polyolefins. In our proposal, we also proposed that flares controlling propane dehydrogenation (PDH) processes be included in the specified subset since the PDH process produces olefins such as propylene. We also proposed at 40 CFR 63.2535(m) to clarify that owners or operators of flares that are not considered to be in the specified subset but are subject to the

flare provisions of 40 CFR 60.18 or 63.11 may elect to comply with the new proposed flare standards in lieu of the provisions of 40 CFR 60.18 or 63.11.

We proposed at 40 CFR 63.2450(e)(5) to directly apply the petroleum refinery flare rule requirements in 40 CFR part 63, subpart CC, to the flares in the specified subset with clarifications, including, but not limited to, specifying that several definitions in 40 CFR part 63, subpart CC, that apply to petroleum refinery flares also apply to the flares in the specified subset, adding a definition and requirements for pressure-assisted multi-point flares, and specifying additional requirements when a gas chromatograph or mass spectrometer is used for compositional analysis. Specifically, we proposed to retain the General Provisions requirements of 40 CFR 63.11(b) and 40 CFR 60.18(b) such that flares in the specified subset operate pilot flame systems continuously and that these flares operate with no visible emissions (except for periods not to exceed a total of 5 minutes during any 2 consecutive hours) when the flare vent gas flow rate is below the smokeless capacity of the flare. We also proposed to consolidate measures related to flare tip velocity and new operational and monitoring requirements related to the combustion zone gas for flares in the specific subset. Further, in keeping with the elimination of the SSM exemption, we proposed a work practice standard related to the visible emissions and velocity limits during periods when a flare in the specified subset is operated above its smokeless capacity (*e.g.,* periods of emergency flaring). We proposed eliminating the cross-references to the General Provisions and instead specifying all operational and monitoring requirements that are intended to apply to the flares in the specified subset in the MACT standards.

In addition, we proposed provisions and clarifications for periods of SSM and bypasses, including PRD releases, bypass lines on closed vent systems, maintenance activities, and certain gaseous streams routed to a fuel gas system to ensure that CAA section 112 standards apply continuously, consistent with *Sierra Club* v. *EPA* 551 F. 3d 1019 (D.C. Cir. 2008). For PRD releases, we proposed definitions at 40 CFR 63.2550 of ''pressure release,'' ''pressure relief device,'' and ''relief valve'' and under CAA section 112(h) we proposed a work practice standard for PRDs at 40 CFR 63.2480(e)(3), (6), and (7) that consists of using at least three prevention measures and performing root cause analysis and corrective action in the event that a PRD does release emissions directly to the atmosphere. (Examples of prevention measures include flow indicators, level indicators, temperature indicators, pressure indicators, routine inspection and maintenance programs or operator training, inherently safer designs or safety instrumentation systems, deluge systems, and staged relief systems where the initial PRD discharges to a control system.) We proposed that PRDs in ethylene oxide service may not vent directly to atmosphere. We also proposed to require that sources monitor PRDs that vent to atmosphere using a system that is capable of identifying and recording the time and duration of each pressure release and of notifying operators that a pressure release has occurred. We proposed at 40 CFR 63.2480(e)(4) that PRDs that vent through a closed vent system to a control device or to a process, fuel gas system, or drain system must meet minimum requirements for the applicable control system. In addition, we proposed at 40 CFR 63.2480(e)(5) that the following types of PRDs would not be subject to the work practice standard for PRDs that vent to the atmosphere: (1) PRDs with a design release pressure of less than 2.5 pounds per square inch gauge (psig); (2) PRDs in heavy liquid service; (3) PRDs that are designed solely to release due to liquid thermal expansion; and (4) pilot-operated and balanced bellows PRDs if the primary release valve associated with the PRD is vented through a control system. Finally, we proposed at 40 CFR 63.2480(e)(8) to require future installation and operation of non-flowing pilot-operated PRDs at all affected sources.

For bypass lines on closed vent systems, we proposed at 40 CFR 63.2450(e)(6) that an owner or operator may not bypass the air pollution control device (APCD) at any time, and if a bypass is used, then the owner or operator must estimate and report the quantity of organic HAP released. We proposed and are taking final action on this revision because bypassing an APCD could result in a large release of regulated organic HAP to the atmosphere (the removal efficiency required by the MON ranges from 95 to 99.9 percent, depending on the type of emission source). The MON requirements we are finalizing thus provide the Agency with the information necessary to evaluate these incidents and determine whether enforcement action is necessary to address such releases to ensure they do not recur. We are also taking final action to allow the use of a cap, blind flange, plug, or second valve on an open-ended valve or line to prevent a bypass. For these reasons, we maintain that the MON as revised is consistent with *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), because the rule requires compliance with emission standards at all times as required by CAA section 112(d) and because the rule includes sufficient monitoring, recordkeeping and reporting requirements to allow the EPA to evaluate and address any unauthorized releases of HAP emissions.

For maintenance activities, we proposed a work practice standard at 40 CFR 63.2455(d)(1) requiring that, prior to opening process equipment to the atmosphere, the equipment must either (1) Be drained and purged to a closed system so that the hydrocarbon content is less than or equal to 10 percent of the LEL; (2) be opened and vented to the atmosphere only if the 10-percent LEL cannot be demonstrated and the pressure is less than or equal to 5 psig, provided there is no active purging of the equipment to the atmosphere until the LEL criterion is met; (3) be opened when there is less than 50 lbs of VOC that may be emitted to the atmosphere; or (4) for installing or removing an equipment blind, depressurize the equipment to 2 psig or less and maintain pressure of the equipment where purge gas enters the equipment at or below 2 psig during the blind flange installation, provided none of the other proposed work practice standards can be met. For cases where an emission source is required to be controlled in the MACT standards but is routed to a fuel gas system, we proposed that any flare receiving gases from that fuel gas system derived from an MCPU that has processes and/or equipment in ethylene oxide service or that produces olefins or polyolefins, and utilizing fuel gas whereby the majority (*i.e.,* 50 percent or more) of the fuel gas in the fuel gas system is derived from an MCPU, comply with the proposed flare operating and monitoring requirements.

More information concerning our proposed requirements under CAA section 112(d)(2) and (3) and 112(h) can be found in section IV.A of the proposal preamble (84 FR 69182, December 17, 2019).

2. How did the revisions pursuant to CAA section 112(d)(2) and (3) and 112(h) change since proposal?

The EPA is finalizing the revisions to the monitoring and operational requirements for flares, as proposed, except that we are not finalizing the work practice standard for velocity exceedances for flares operating above

their smokeless capacity. We are also clarifying in the final rule that a ''flare that controls ethylene oxide emissions'' is a flare that controls ethylene oxide emissions from affected sources in ethylene oxide service as defined in 40 CFR 63.2550. In addition, we are clarifying in the final rule that ''an MCPU that produces olefins or polyolefins'' include only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product; by-products and impurities as defined in 40 CFR 63.101, as well as wastes and trace contaminants, are not considered products.

Also, we are adding a separate degassing standard in the final rule at 40 CFR 63.2470(f) for storage vessels subject to control requirements based on comments that owners or operators have historically considered degassing emissions from shutdown of storage vessels to be covered by their SSM plans per 40 CFR 63.63.2525(j) and relied on the language in 40 CFR 63.6(e)(1) and 40 CFR 63.2450(a)(1) that back-up control devices are not required. The standard requires owners or operators to control degassing emissions for floating roof and fixed roof storage vessels until the vapor space concentration is less than 10 percent of the LEL. Storage vessels may be vented to the atmosphere once the storage vessel degassing concentration threshold is met (*i.e.,* 10-percent LEL) and all standing liquid has been removed from the vessel to the extent practical.

3. What key comments did we receive on the proposal revisions pursuant to CAA section 112(d)(2) and (3) and 112(h), and what are our responses?

This section provides comment and responses for the key comments received regarding our proposed revisions for flares and clarifications for periods of SSM, including PRD releases and storage vessel emptying and degassing. Other comment summaries and the EPA's responses for additional issues raised regarding these activities, as well as issues raised regarding our proposed revisions for bypass lines on closed vent systems, maintenance activities, and certain gaseous streams routed to a fuel gas system, can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

a. Flares

Comment: We received comments in support of our proposal to establish similar requirements for flares (controlling ethylene oxide or emissions from processes that produce olefins and/or polyolefins) used in the Miscellaneous Organic Chemical Manufacturing source category as the flare requirements established in the 2015 Petroleum Refinery NESHAP, including the incorporation of the net heating value of the combustion zone gas (NHVcz) calculation and limits. One commenter said they supported the proposed strengthened operational and monitoring requirements because of the toxic nature of ethylene oxide and the photochemical reactivity of the olefins and polyolefins emissions.

Another commenter cited various enforcement cases where the EPA found flare efficiency problems and applied flare operational and monitoring improvements to chemical plants. The commenter said that because MON sources do not currently have separate flare management plan requirements (as refineries do under CAA section 111 NSPS standards), it is particularly important and necessary for the EPA to update the flare requirements in this rule to assure that flares are working correctly to reduce HAP emissions. Also, the commenter reiterated the EPA's determination that measuring the net heating value of the flare gas, as it enters the flares, is insufficient to determine combustibility because facilities add steam and other gases not accounted for and that flare performance data shows that the net heating value of vent gas in the combustion zone must reach at least 270 British thermal units per standard cubic foot (Btu/scf). Some commenters also supported the EPA's proposal ''that owners or operators may use a corrected heat content of 1,212 Btu/scf for hydrogen, instead of 274 Btu/scf, to demonstrate compliance with the NHVcz operating limit,'' because the data show that the control efficiency of a flare drops off significantly below this level. However, the commenters also suggested other improvements to the proposed flared revisions. The commenters recommended that the EPA also consider the following measures to help assure compliance with 98-percent destruction efficiency and said that these measures should be evaluated under CAA section 112(d)(6).

- Revise the standards to account for ''developments'' that improve emissions controls by eliminating or drastically reducing routine flaring, such as augmented flare capacity;
- The HAP emission rates from flares during malfunctions when process gases are routed to flares from process equipment should not be less stringent than the emission limits that apply to such units during normal operations.
- Set further limits on routine flaring that comply with CAA section 112(d)(2) and (3), and 112(f).
- Require continuous video monitoring and recording for flares equipped with video monitoring and flares that vent more than 1 million scf per day.[20]
- Set limits on flaring that require flare gas recovery and other steps to reduce regular and routine flaring.

Response: Except for minor clarifications discussed in the response to comment document for this rulemaking, the EPA is finalizing the flare operational and monitoring requirements at 40 CFR 63.2450(e)(5), as proposed, as supported by several commenters. We disagree with one commenter's request that we mandate additional measures to ensure 98-percent flare destruction efficiency on top of those being finalized in this action under our CAA section 112(d)(2) and (3) authority. Flares are one of many APCDs that owners or operators of MCPUs can use to control HAP emissions from the Miscellaneous Organic Chemical Manufacturing source category and are not specific affected emission sources in the Miscellaneous Organic Chemical Manufacturing source category; thus, the flare requirements we are finalizing are already designed to ensure flares meet a minimum destruction efficiency of 98 percent, consistent with the MACT control requirements.

We disagree with commenters that we should impose the additional measures for flares under our CAA section 112(d)(6) authority because the revisions to the flare requirements are associated with compliance with the MACT standards established pursuant to CAA sections 112(d)(2) and (3). The rulemaking record contains the analyses on options we analyzed for our technology review, and owners or operators of MCPUs can chose from a variety of APCDs to demonstrate

[20] Commenter provided the following reference: See 84 FR 54296; BAAQMD sec. 12–11–507: Requiring continuous video monitoring and recording for flares equipped with video monitoring and flares with vent gas more than 1 million scf/day; SCAQMD Rule 1118(g)(7): Requiring continuous video monitoring and recording; Consent Decree, *United States of America* v. *Marathon Petroleum Company LP et al.,* No. 12–cv–11544 (E.D. Mich.) (April 5, 2012); Consent Decree, *United States of America et al.* v. *BP Products North America Inc.,* No. 12–cv–0207 (N.D. Ind.) (May 23, 2012); Consent Decree, *United States of America* v. *Shell Oil Company et al.,* No. 13–cv–2009 (S.D. Tex.) (July 10, 2013); Consent Decree, *United States of America* v. *Flint Hills Resources Port Arthur, LLC,* No. 14–cv–0169, at 12 (E.D. Tex.) (March 20, 2014).

compliance with the underlying MACT standards. Notably the commenter does not recommend similar actions to minimize or eliminate the use of thermal oxidizers, carbon absorbers, or other control devices that may be employed to control HAP emissions from the affected emission sources at an MCPU. Eliminating the routine use of flares as an acceptable APCD would only increase the use of these other types of APCD (at potentially significant cost) without any net emissions reductions from the MCPU (provided that the flare is meeting the required control efficiency). In addition, flare gas recovery has not been demonstrated at MCPU in the Miscellaneous Organic Chemical Manufacturing source category, and commenters did not provide sufficient information about requiring use of such systems specific to this source category.

We disagree with the commenter's specific request to require continuous video monitoring and recording for flares equipped with video monitoring and flares that vent more than 1 MMscf/day. We are not removing the requirement to conduct EPA Method 22 monitoring because it has always been required for flares; however, because EPA Method 22 does not allow the use of a video camera, we have provided for the use of video camera surveillance monitoring in the final rule as an alternative to EPA Method 22 monitoring. Observation via the video camera feed can be conducted readily throughout the day and will allow the operators of the flare to watch for visible emissions at the same time they are adjusting the flare operations. We note that in order for an owner or operator to be able to use the video camera surveillance monitoring option, the owner or operator must continuously record (at least one frame every 15 seconds with time and date stamps) images of the flare flame at a reasonable distance above the flare flame and at an angle suitable for visual emissions observations. The owner or operator must also provide real-time video surveillance camera output to the control room or other continuously manned location where the camera images may be viewed at any time.

Lastly, with respect to consent decrees cited by the commenter, we note that the requirements in consent decrees are negotiated settlements and are not based on any analysis required in CAA section 112 and do not factor in nationwide impacts specific to a source category of concern, which in this case is the Miscellaneous Organic Chemical Manufacturing source category.

Comment: Commenters requested the EPA clarify in 40 CFR 63.2450(e)(5) that the requirements only apply to (1) flares controlling emissions from sources in ethylene oxide service as defined in 40 CFR 63.2550 and (2) flares used as an APCD to comply with the emission limits and work practice standards in Tables 1, 2, 4, and 5 to 40 CFR part 63, subpart FFFF, for emission sources located at MCPUs that produce olefins and/or polyolefins. A commenter said that the introductory language in 40 CFR 63.2450(e)(5) is ambiguous and appears to indicate that a flare that controls any amount of ethylene oxide or any amount of other HAP from olefins or polyolefins production processes would be subject to the proposed requirements. In addition, the commenter requested that the EPA limit the applicability of the revised provisions to those MCPUs producing lighter olefins and polyolefins and that heavy olefin (*e.g.,* hexene) and heavy polyolefin (*e.g.,* polybutene) production should be excluded because heavier materials used in such processes have much less potential to be flared. The commenter requested that the EPA define the phrase ''MCPUs that produce olefins or polyolefins'' and said that MCPUs may generate olefins or polyolefins as a by-product or impurity and these small amounts of materials do not justify the compliance costs associated with meeting the new flare requirements. The commenter recommended the EPA adopt definitions similar to those for ''Product, By-product,'' and ''Impurity'' found in the HON (*i.e.,* 40 CFR 63.101).

Other commenters said the EPA must apply the proposed flare improvements to all MON flares, not just the subset that controls ethylene oxide and emissions from olefin/polyolefin processes. One commenter said that the refinery flare requirements, as proposed, will only apply to 16 of 145 flares in the source category and reiterated that this is less than 10 percent of the flares in the Miscellaneous Organic Chemical Manufacturing source category. The commenter said the EPA did not sufficiently explain why the flare improvements should not be applied to all MON flares.

Response: First, as a general matter, the Miscellaneous Organic Chemical Manufacturing source category broadly encompasses a wide variety of chemical production processes not covered elsewhere under other 40 CFR part 63 NESHAP and, as such, is a ''catch all'' for a wide variety of processes producing various types of chemical products. The primary goal of applying the new suite of flare requirements to a certain flare subset is two-fold: (1) To ensure continuous compliance with the MON MACT standards at all times for the largest flare systems in the source category where the Agency has compelling data that show that the flare types and vent gases being controlled (*e.g.,* olefinic vent gases that contain ethylene and/or propylene) could have deteriorated flare performance issues, and (2) to ensure continuous compliance with the MON MACT standards at all times for flare systems controlling ethylene oxide, the cancer risk driving HAP for the source category. In particular, when the EPA reviewed available data about flare APCDs being used in the Miscellaneous Organic Chemical Manufacturing source category and the potential for deteriorated combustion efficiencies to occur during certain modes of operation (*e.g.,* over-assisting steam-assisted flares), we determined that vent gases consisting of olefinic material can be over-assisted and that flare performance for these types of MCPUs could be diminished (*i.e.,* consistent with the passive fourier transfer infrared spectrometry (PFTIR) test data reviewed and that formed the basis of the Petroleum Refinery requirements at 40 CFR part 63, subpart CC, we cross-reference in this final rule for the MON). In addition, the EPA has recently reviewed and approved a number of AMEL requests from MON facilities that produce olefins/polyolefins, and this subset of facilities in the Miscellaneous Organic Chemical Manufacturing source category comprises the largest flare systems in the source category, making issues of deteriorated flare performance of particular concern. With respect to flares controlling emissions of ethylene oxide, the EPA also wanted to ensure that these flare systems would be subject to more stringent compliance assurance requirements to ensure over-assisting does not occur for these flare types given risks associated with ethylene oxide in the source category. Thus, these two criteria were chosen to constitute the basis of our flare subset given both the data before us and the concern for potential risk issues if deteriorated flare performance were to occur for flares controlling emissions of ethylene oxide from the source category. Given that we do not have sufficient data about the types of flares and flare vent gases that the other various MCPUs outside the flare subset would be controlling, we are unable to determine whether the new suite of flare requirements would be necessary or warranted as the existing suite of flare requirements may be sufficient for these

other flares. Commenters did not provide the Agency with any information about this, including test data, flare vent gas characteristics, and specific instances of deteriorated flare performance for flares outside the flare subset, thus we disagree that we should broadly apply these new flare requirements to all flares in the source category without this information. We note, however, that we proposed and are finalizing as an alternative that owners or operators of flares outside the flare subset may opt to comply with the new suite of flare requirements should they choose.

With respect to comments requesting the EPA to clarify what was meant when referring to production of olefins and/or polyolefins, we are adding a definition for ''MCPUs that produce olefins or polyolefins'' for purposes of the new suite of flare requirements only and clarifying that these MCPUs include production of ethylene, propylene, polyethylene, and polypropylene given that these are the largest flare systems in the Miscellaneous Organic Chemical Manufacturing source category and because they are controlling olefinic vent gases that contain ethylene and propylene, which have been shown in our data to exhibit certain operating scenarios where over-assisting and deteriorated flare performance could occur.

Lastly, we agree with commenters that the language at 40 CFR 63.2450(e)(5) could be construed as ambiguous for purposes of controlling ethylene oxide emissions. As such, we are clarifying in the rule text that our intent was to control all emissions generated from affected sources ''in ethylene oxide service,'' as that term is defined in the final rule.

Comment: We received comments in support of and against the proposed work practice requirements for visible emissions and flare tip velocity. One commenter said that MON flares operate similarly to refinery flares in that MON flares are typically designed with a ''smokeless capacity'' for normal operations and a ''hydraulic load capacity'' to handle large volumes of flare gas in an emergency. The commenter said that it was reasonable for the EPA to use smoking and tip velocity events reported for ethylene production and refineries to develop emergency flaring provisions for the Miscellaneous Organic Chemical Manufacturing source category because the data on the number of visible emissions events and velocity exceedances for MON flares are not comprehensive of all MON facilities in the subset identified by the EPA. However, the commenter said that because ethylene flares are twice as likely to have visible emissions events as refinery flares, and because it is reasonable to use smoking event data for ethylene flares to represent MON flares, the EPA should set the backstop for the work practice standard to 6 smoking events in 3 years for MON flares in the identified subset.

Another commenter objected to the EPA's proposed emergency flaring provisions for smoking flares and said that the provisions are arbitrary and capricious because they do not meet the requirement from CAA section 112(h) that work practice standards be consistent with CAA section 112(d)(2) and (d)(3). The commenter argued that the EPA's assumption regarding the frequency of emergency flaring events using events at refineries and ethylene production facilities does not satisfy the requirement in CAA section 112(d)(2) that the Administrator ''determine'' what is achievable regarding the frequency of emergency flaring events. The commenter said the EPA's reliance on data from refineries and ethylene production facilities, and lack of analysis of the frequency of emergency flaring events at MON facilities, means that the exemption provision violates the CAA section 112(d) requirement that the EPA determine what is achievable for sources ''in the category or subcategory to which such emission standard applies.'' The commenter requested that the EPA remove the emergency flaring provisions because the EPA needs to collect data from MON sources to set a standard that could satisfy CAA section 112(d)(2) and (d)(3).

In addition, the commenter said that even though the visible emission exemption at issue is for smoking flare events when flares are operating above their smokeless capacity, the EPA (in the present proposed rule, as well as in its analyses regarding refinery and ethylene production flares) only reached conclusions and analyzed data regarding what is achievable for smoking flare events regardless of whether the flares were operating above or below their smokeless capacity. The commenter argued that the EPA has not determined what is achievable for flares when operating above their smokeless capacity. The commenter also said the EPA has not performed any analysis of how often the best performers would exceed flare tip velocity limits when operating above smokeless capacity, and the EPA has only purported to analyze smoking flare events (without regard to whether the events occurred above smokeless capacity). The commenter stated that the EPA also ignored data that contradict its conclusion regarding the exemption allowing flare tip velocity events because the ACC data that the EPA relied upon to establish the emergency flaring exemption in the ethylene production proposal reported no tip velocity events among any of the 45 flares from the ACC survey. The commenter contended that the ACC data suggest that the best performing flares (at least at ethylene production facilities) would have zero tip velocity exceedances over three years, meaning that the EPA's conclusion that the best performers would have one or two exceedances over that same period is arbitrary and capricious and contrary to CAA section 112(d). The commenter stated that, unlike the MON proposed rule, the EPA finalized in the Ethylene Production RTR rulemaking the requirement that the maximum flare tip velocity operating limit applies at all times.

Response: We are taking final action on the proposed work practice requirements for visible emissions and flare tip velocity as several commenters suggested. We disagree that we should set the backstop for the work practice standard to 6 smoking events in 3 years for MON flares in the identified subset. The commenter did not provide enough data (*i.e.,* information on visible emissions from MON flares in the identified subset) for the EPA to justify revising the proposed requirements. We also disagree with another commenter that we did not analyze the frequency of emergency flaring events at MON facilities and that reliance on data from refineries and ethylene production facilities means that the exemption provision violates the CAA section 112(d) requirement that the EPA determine what is achievable for sources ''in the category or subcategory to which such emission standard applies.'' We contend that the data used in our analysis represents the best available data available to the agency for the Miscellaneous Organic Chemical Manufacturing Source Category. As stated in our technical memorandum, *Control Option Impacts for Flares Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0006), although ACC provided some information about visible emissions events and velocity exceedances for MON flares, the data are not comprehensive of all MON flares in the identified subset. Therefore, we did not use the ACC data to determine the number of smoking and tip velocity events that we used in our analysis for

the Miscellaneous Organic Chemical Manufacturing source category, but rather this information is based on smoking and tip velocity events reported for two different source categories (refineries and ethylene production). Best performing flares at refineries have events once every 6 years, and ethylene flare best performers have events once every 7 years. We noted that some flares control process gases from both the Miscellaneous Organic Chemical Manufacturing source category and from the Ethylene Production source category at the same facility. Therefore, we surmised that it is likely that MON flares in the identified subset would have a visible emissions event between every 6 and 7 years. As a conservative approach, we then concluded the best performing MON flares in the identified subset have a visible emissions event once every 7 years. Even if the best-performing flare ''typically'' only has one event every 7 years, the fact that visible emissions events are random by nature (unpredictable, not under the direct control of the owner or operator) makes it difficult to use a short term time span to evaluate a backstop to ensure an effective work practice standard. Thus, when one considers a longer time span of 20 years, our analysis shows that 3 smoking events in 3 years would appear to be ''achievable'' for the average of the best performing flares. That said, we do acknowledge that the data we received from ACC's survey from the Ethylene Production source category identifies zero exceedances of the flare tip velocity during a smoking event. Also, the MON-specific data that ACC provided is limited to only one MON facility, of which 44 of these events were associated with pressure-assisted flares, and no velocity events were reported by any other MON site. Thus, we agree with the commenter that our proposed determination of the frequency of these velocity events at the best performing sources is not supported, and we are not finalizing the proposed work practice standard for when the flare vent gas flow rate exceeds the smokeless capacity of the flare and the tip velocity exceeds the maximum flare tip velocity operating limit. Instead, we are finalizing provisions that require compliance with the maximum flare tip velocity operating limit at all times, regardless of whether the flare is operating above its smokeless capacity.

b. PRDs

Comment: Several commenters supported the PRD work practice requirements, agreeing it is technically and economically infeasible to establish emission limitations for PRDs that are not designed to vent through a control system. The commenters added that the EPA's approach meets their obligations under CAA section 112. One commenter noted that even states that have stringently regulated PRDs, such as California, have not established numerical emissions limits. The commenter added that because these events are triggered by a variety of non-routine process conditions across a variety of different processes, there is no MACT-level technology that can be applied to this category of PRDs to limit emissions to a certain quantity or concentration. The commenter noted that the MACT requirements should be consistent with other regulatory obligations such as the OSHA Process Safety Management (PSM) program and the EPA CAP program.

Another commenter contended that work practice standards are only allowed in lieu of numerical emission standards under narrow circumstances, and the EPA may not set work practice standard unless the EPA determines that the pollutant cannot be emitted ''through a conveyance designed and constructed to emit or capture such pollutant'' or that ''application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations.'' The commenter added that even when the EPA sets a work practice standard, such a standard must require the ''maximum'' degree of emission reduction ''achievable'' and still be consistent with section 112(d)(2) and (3) to apply continuously. The commenter added that work practice standards for PRDs are not allowed because traditional emission restrictions are feasible to restrict the excess emissions the EPA seeks to authorize. The commenter noted that CAA section 112(h) requires the EPA to make a very specific finding that numeric emissions are infeasible, and the EPA has not satisfied that requirement for PRDs. The commenter claimed that the EPA's assertion that emissions cannot be measured is contradicted by its requirement that sources calculate their emissions during any PRD release to the atmosphere, and the EPA's reporting and recordkeeping requirements mandate facilities ''calculate the quantity of organic HAP released during each pressure release event.'' The commenter also noted that local jurisdictions require monitoring to measure such releases.

A commenter contended that because PRDs at MON sources are currently uncontrolled, the EPA must set a standard that satisfies CAA section (d)(2) and (3) and reflects what the relevant best-performing existing sources have ''achieved'' and the ''maximum achievable degree of emission reduction.'' The commenter continued that the EPA must set the floor by assessing the emissions limitation achieved by the best performing 12 percent of existing sources and that cost cannot be considered in setting the MACT floor, per CAA section (d)(3). The commenter contended the EPA must set a zero-emission limit for all PRDs because the best-performing PRDs emit nothing. The commenter stated that in the proposed rule, the EPA has not attempted to evaluate the actual performance of PRDs at MON sources. The commenter added that in the absence of emissions data, the EPA may infer that the MACT floor is at least as stringent as an existing regulatory limit, such as California's South Coast Air Quality Management District (SCAQMD) and the Bay Area Air Quality Management District (BAAQMD) for similar sources. The commenter noted that both agencies have adopted more stringent emission limitations and leak and repair programs. The commenter also added that the EPA has ample emissions data demonstrating that emissions of at least 12 percent of existing PRDs nationwide reflect at least the use of a well-performing flare. As an example, the commenter stated that the TCEQ data the EPA relied on in the ethylene production rule demonstrated that 23 percent of facilities had no atmospheric releases on a properly operating PRD. Another commenter also said the EPA should evaluate the data that SCAQMD is considering in that rulemaking and further strengthen the requirements for MON sources.[21]

One commenter contended that the EPA did not analyze the cost of construction and installation of continuous monitoring systems in order to measure release events for PRDs that vent to atmosphere. The commenter noted that the EPA's reporting and recordkeeping requirements mandate facilities ''calculate the quantity of organic [hazardous air pollutants] released during each pressure release event'' and that a SCAQMD report

[21] Commenter provided the following reference: SCAQMD, Rule and Control Measure Forecast (Mar 6, 2020), *http://www.aqmd.gov/docs/default-source/Agendas/Governing-Board/2020/2020-mar6-016.pdf?sfvrsn=6,* (stating that SCAQMD is considering proposed revisions to ''improve the effectiveness, enforceability, and clarity of the rule. Other proposed amendments may be needed to further reduce emissions from operations, implement early leak detection, odor minimization plans, and enhanced emissions and chemical reporting'').

found that ''new (wireless) technology allows continuous monitoring of PRDs without significant capital expense and makes it easy for operators to identify valve leaks.'' The commenter added that there are multiple vendors of this technology, including one vendor with whom the EPA met during the refineries rulemaking, and this technology is already in use at refineries in the United States. The commenter claimed that refineries have found that implementing this kind of monitoring technology saves money. The commenter added that in the ethylene production rulemaking, the EPA relied on TCEQ data from seven ethylene production facilities that reported the quantity of HAP emissions released during specific PRD release events indicating that not only is it possible to measure PRD emissions, but also that they actually have been measured and that the EPA itself acknowledges this fact.

Response: We disagree with some commenters' assessment that numeric emission limit standards are feasible and must be established for PRDs that vent to the atmosphere. We are finalizing a work practice standard for PRDs, as proposed, that consists of using at least three prevention measures and performing root cause analysis and corrective action in the event that a PRD does release emissions directly to the atmosphere. We also maintain the rationale provided in the proposal preamble (84 FR 69207, December 17, 2019) for this work practice standard, where we specifically considered the issue related to constructing a conveyance and quantitatively measuring PRD releases and concluded that these measures were not practicable and that a work practice standard was appropriate. Owners or operators can estimate the quantity of HAP emissions released during a PRD release event based on vessel operating conditions (temperature and pressure) and vessel contents when a release occurs, but these estimates do not constitute a measurement of emissions or emission rate within the meaning of CAA section 112(h). The monitoring technology suggested by the commenter is adequate for identifying PRD releases and is one of the acceptable methods that facility owners or operators may use to comply with the continuous monitoring requirement. However, we disagree that it is adequate for accurately measuring emissions for purposes of determining compliance with a numeric emission standard. For example, the technology cited by the commenter is a wireless monitor that provides an indication that a PRD release has occurred, but it does not provide information on either release quantity or composition. PRD release events are characterized by short, high pressure, non-steady state conditions that make such releases difficult to quantitatively measure. As discussed in the proposal preamble (84 FR 69207, December 17, 2019), we have not identified any available, technically feasible CEMS that can accurately determine a mass release quantity of VOC or HAP given the flow, composition, and composition variability of potential PRD releases that vent to the atmosphere from MCPUs. Therefore, it is also economically infeasible at this time to establish emission limitations for PRDs given that no such system exists. As such, we maintain our position that the application of a work practice standard is appropriate for PRDs.

As a general matter, CAA section 112 requires MACT for existing sources to be no less stringent than ''the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information) . . .'' [(CAA section 112(d)(3)(A)]. ''Emission limitation'' is defined in the CAA as ''. . . a requirement established by the State or Administrator which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to operation or maintenance of a source to assure continuous emission reduction, and any design, equipment, work practice, or operational standard promulgated under this chapter'' [CAA section 302(k)]. The EPA specifically considers existing rules from state and local authorities in identifying the ''emission limitations'' for a given source. We then identify the best performers to identify the MACT floor (the no less stringent than level) for that source. The EPA identified the requirements established in the SCAQMD and BAAQMD rules,[22] and the Chemical Accident Prevent Provisions rule (40 CFR part 68) as the basis of the MACT floor because they represented the requirements applicable to the best performing sources. Work practice standards are established in place of a numeric limit where it is not feasible to establish such limits. Thus, in a case such as this, where the EPA has determined that it is appropriate to establish work practice standards, it was reasonable for the EPA to identify the rules that impose the most stringent requirements and, thus, represent what applies to the best performers, and then to apply the requirements from those rules as MACT.

We recognize that the proposed standard for PRDs did not exactly mirror the SCAQMD, BAAQMD, or Chemical Accident Prevent Provisions rules, but we consider the requirements to be comparable. For example, we did not include a provision similar to that in the SCAQMD rule that excludes releases less than 500 lbs/day from the requirement to perform a root cause analysis; that provision in the SCAQMD rule does not include any other obligation to reduce the number of these events. Similarly, we did not include a provision that only catastrophic PRD releases must be investigated. Rather than allowing unlimited releases less than 500 lbs/day or that are not considered catastrophic, we require a root cause analysis for releases of any size. Because we count small releases that the SCAQMD rule does not regulate at all, we considered it reasonable to provide a higher number of releases prior to considering the owner or operator to be in violation of the work practice standard. We also adopted the three prevention measures requirements in the BAAQMD rule with limited modifications. We also note that a facility cannot simply choose to release pollutants from a PRD; any release that is caused willfully or caused by negligence or operator error is considered a violation.

Comment: Two commenters supported subcategorizing PRDs and agreed with the EPA's rationale for doing so. However, one commenter contended that the EPA has unlawfully categorized PRDs by control (*i.e.,* PRDs that vent through a closed vent system to a control device or to a process, fuel gas system, or drain system and PRDs that vent to the atmosphere). The commenter added that the best-controlled PRDs are routed to processes with no discharge to the environment, and well-controlled PRDs are vented to a control system rather than directly to the atmosphere. The commenter stated that the EPA must determine the appropriate MACT floor for new and existing PRDs based on the best performing PRDs and also require ''beyond the floor'' options, but because PRDs nationwide reflect at least the use of a control system, the EPA may not establish a limitation that is less stringent than venting to a control system. The commenter contended that because the best-controlled PRDs have

[22] While there are not MON facilities in the SCAQMD or BAAQMD, as stated in the proposal preamble (84 FR 29207), we believe that MON facilities are complying with these rules via company-wide best practices. There are companies that own MON facilities and petroleum refineries, and there are petroleum refineries located in these AQMDs.

no emissions, the EPA must set a zero-emission limit for all PRDs.

One commenter also contended that the EPA did not explain why additional flares cannot be installed by MON facilities to meet a standard prohibiting uncontrolled PRD releases. The commenter stated that the EPA did not estimate the number of new flares that would be installed, based on data of the number of atmospheric PRDs reported at MON facilities.

Response: Regarding subcategorization of PRDs, the only information we have available about when PRD releases occur is from those PRDs that release directly to atmosphere (see the technical memorandum, *Review of Regulatory Alternatives for Certain Vent Streams in the Miscellaneous Organic Chemical Manufacturing Source Category,* available in the docket for this rulemaking, see Docket Item No. EPA–HQ–OAR–2018–0746–0010). The work practice standard we are finalizing provides a comprehensive program to manage entire populations of PRDs; includes prevention measures, continuous monitoring, root cause analysis, and corrective actions; and addresses the potential for violations for multiple releases over a 3-year period. We followed the requirements of section 112 of the CAA, including CAA section 112(h), in establishing what work practice constituted the MACT floor. We provide further details on our rationale to develop a work practice standard in previous responses to comments in this section of this preamble and the preamble to the proposed rule.

We disagree with the comment that the EPA did not explain why additional flares could not be installed to control releases from PRDs. We conducted a beyond-the-floor analysis at proposal that examined the option of controlling all PRDs with a control device. 84 FR 69209. As part of this analysis, we estimated for all MON facilities, assuming 25 percent to 50 percent of PRDs already vent to a control device, the capital cost for controlling the remaining PRDs ranges from $2.54 billion to $5.07 billion, and the annualized cost ranges from $330 million to $660 million. Because the incremental cost effectiveness for requiring control of all PRDs that vent to atmosphere exceeds $80 million per ton of HAP reduced, the beyond-the-floor option was determined not to be cost-effective. Details of the beyond-the-floor analysis are available in the memorandum, *Review of Regulatory Alternatives for Certain Vent Streams in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0010).

Comment: We received comments in support of and against the proposed requirements allowing PRDs to discharge to the atmosphere. Some commenters supported allowing a limited number of PRD releases at MON facilities. The commenters supported the EPA's assessment that even at the best performing sources, releases from PRDs are likely to occur and cannot be safely or economically routed to a control device. Two commenters contended there was a wide variety of situations that can trigger a PRD actuation and noted it was impossible to predict which PRDs will release during a given year. One commenter opposed any limit on the number of PRD releases because they are needed for safety reasons. However, the commenter added that if the EPA is going to finalize a limit on the number of authorized PRD venting events, they supported allowing more than one release in a 3 calendar year period.

Two commenters identified several situations where PRDs are designed to vent to the atmosphere instead of a flare or other control device due to safety concerns. One commenter also identified situations where it was technically not possible to collect discharges from PRDs. One commenter supported the EPA's conclusion that it was not cost effective to control all PRDs that vent to the atmosphere.

Another commenter noted that PRDs on process equipment such as distillation columns and steamers are typically intended for emergency venting, and these devices are the last (mechanical) line of defense to avoid over-pressurization situations. The commenter added that pollution control devices are intended for normal process operations and are not commonly designed to handle the flow that would result from an emergency PRD release. The commenter concluded that the capture of releases from emergency over-pressurizations has the potential to create a new hazard.

One commenter opposed allowing PRDs to discharge to the atmosphere. The commenter stated that the EPA cannot use CAA section 112(h) to circumvent the emission standards of equipment connected to PRDs and smoking flares through uncontrolled releases from these devices. The commenter cited the court decision *U.S. Sugar Corp.* v. *EPA, 830 F.3d* at 608 (D.C. Cir. 2016) that exemptions ''cannot be framed in simple numerical terms, as, say, an allowance of four excessive discharges per year,'' as doing so would give emitters ''a license to dump wastes at will on several occasions annually,'' and *Weyerhaeuser Co.* v. *Costle, 590 F.2d* at 1011, 1057 (D.C. Cir. 1978) that ''no control'' is not a standard—it is an exemption. The commenter continued to cite *Weyerhaeuser Co.* v. *Costle* that malfunctions and *force majeure* events are appropriately dealt with through ''the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.'' The commenter contended that finalizing these exemptions would incentivize facilities to install redundant PRDs or flares, and operators could cycle through PRDs, sealing off each one after a release event to avoid repeated violations of the underlying equipment's emission standards. The commenter added that emissions could be routed away from controlling flares to an endless number of cycling pressure release devices resulting in unlimited emissions with no technical violation. The commenter concluded that treating releases from PRDs and smoking flares as violations would incentivize operators to do the planning/maintenance, etc., to eliminate the root causes of these releases.

The commenter stated that allowing PRD releases is not consistent with the technology-forcing requirements from CAA section 112(d) and is arbitrary and capricious. The commenter contended that neither the proposed rule nor the EPA's supporting memorandum regarding the work practice standards for PRD releases to the atmosphere discusses whether the number of uncontrolled releases that would be a violation of the standard reflects what is achievable under CAA section 112(d). The commenter added that the exemption violates CAA sections 112(d) and (h) because the EPA has not analyzed what the best performers can achieve with respect to the number of uncontrolled PRD releases to the atmosphere. The commenter contended that the EPA's conclusions were based on a Monte Carlo analysis of random rare events conducted for the Petroleum Refinery Sector rule, for smoking flare events—not PRD releases. The commenter added that the EPA has conducted no analysis of how often the best performing MON facilities have uncontrolled PRD releases to the atmosphere. The commenter concluded that because the EPA did not analyze the rate of PRD releases at MON facilities, the EPA's exemption for PRD releases to the atmosphere is contrary to CAA section 112(h) in that work practice standards be ''consistent with the provisions of subsection (d) or (f).'' The commenter noted that CAA section

112(d) mandates that standards require the ''maximum'' degree of reduction in emissions that the Administrator ''determines is achievable'' for sources ''in the category or subcategory to which such emission standard applies.''

The commenter added that the EPA did not ''determine'' what is ''achievable'' for PRDs, as required by CAA section 112(d)(2) through (3), because the EPA only analyzed what is achievable for flares. The commenter contended that PRDs are not flares, and vice versa, and PRDs could release to the atmosphere at much different rates from the rates at which flares have smoking events. The commenter stated that even if the EPA could lawfully and non-arbitrarily base the limit on MON PRD releases to the atmosphere on the rate at which flares at refineries supposedly have smoking events, the industry data and analysis that the EPA relies upon to try to craft the exemption has problems that also render it contrary to statutory requirements and is arbitrary and capricious. The commenter explained that the analysis began by relying on an unsubstantiated industry claim that an American Petroleum Institute and American Fuel & Petrochemical Manufacturers survey of 148 flares (which industry said was around 30 percent of flares) showed that, on average, a flare will have a smoking event once every 4.4 years. The commenter added that working from the unsubstantiated industry rate of one event every 4.4 years, the EPA then just assumed without support that the best performers would have an event once in every six years (*e.g.,* better than the average of once every 4.4 years). The commenter stated that the EPA then used that assumed and unsubstantiated once-per-six-years frequency to conduct its Monte Carlo analysis. The commenter contended that the EPA's assumption that the best performers would have one event every six years cannot satisfy CAA section 112(d)'s command that the agency determine what the best performers can achieve, nor does that assumption satisfy the requirements that the agency engage in non-arbitrary rulemaking and support its factual determinations with substantial evidence. The commenter also added that the assumptions that the EPA made regarding the rate of PRD releases to the atmosphere in establishing the exemption conflict with the assumptions that the EPA made regarding those releases in calculating the cost for MON facilities to implement the work practice standard, rendering the exemption arbitrary and capricious. The commenter stated that the EPA based the PRD exemption on an analysis that assumed that the best performing flare would have a 16.7-percent probability of having an event every year, and the cost analysis assumed that only 10 percent of PRDs at MON facilities would have a release every year. The commenter also added that information collected for its recent proposed NESHAP rule for ethylene production facilities showed that only 4.4 percent of PRDs in that source category would release to the atmosphere annually. The commenter stated that the EPA's cost analysis only looked to the release rates for all PRDs and not the best-performing ones. The commenter stated that the best performers would presumably release to the atmosphere even less frequently. The commenter added that compliance data for refinery PRDs shows that those devices release to the atmosphere far less frequently than the EPA assumes and that the best-performing uncontrolled PRDs are likely to have no atmospheric releases over a 3-year period. Another commenter concluded that the EPA's proposal to give each uncontrolled PRD one or two free passes before an atmospheric release becomes a deviation is inconsistent with CAA section 112(d)(2) and (3) and arbitrary and capricious. The commenter reviewed some compliance reports from calendar year 2019 for refineries and determined that among the 998 uncontrolled PRDs, there was only one 3-minute release to the atmosphere. The commenter calculated that these 998 uncontrolled PRDs would experience only 7.2 atmospheric releases (or less) over 3 years, and an average of 0.007 (or less) releases per uncontrolled PRD over 3 years. The commenter concluded that the average PRD from the best performers has zero releases to the atmosphere over 3 years.

Response: The EPA is taking final action on the proposed PRD work practice standards as requested in a number of comment letters.

We disagree with the commenter that stated that work practice standards are not appropriate for PRD releases in the Miscellaneous Organic Chemical Manufacturing source category. At proposal, the EPA provided extensive discussions on why it was appropriate to establish a work practice standard for PRDs that vent to atmosphere, under CAA section 112(h). 84 FR 69206–69209, December 17, 2019. We explained that no MON facility is subject to numeric emission limits for PRDs that vent to the atmosphere. We posited that it was not appropriate to subject PRDs that vent to the atmosphere to numeric emission limits due to technological and economical limitations that make it impracticable to measure emissions from such PRDs. We further explained that CAA section 112(h)(1) allows the EPA to prescribe a work practice standard or other requirement, consistent with the provisions of CAA section 112(d) or (f), in those cases where, in the judgment of the Administrator, it is not feasible to enforce an emission standard. Additionally, we explained that CAA section 112(h)(2)(B) defines the term ''not feasible'' in this context as meaning that ''the application of measurement technology to a particular class of sources is not practicable due to technological and economic limitations.'' We also noted that the basis of the work practice standards promulgated for PRD releases in the Petroleum Refinery Sector RTR (80 FR 75178, December 1, 2015) were our underlying basis for the proposed work practice standards at MON facilities.

With regard to the comments about the PRDs and the smoking flare requirements being exemptions, we note that CAA section 112 standards apply at all times to PRDs and to flares controlling vent gas streams from affected emission sources at MON facilities. For PRDs, facilities must implement a system consisting of at least three redundant prevention measures to minimize releases and must monitor PRDs for any releases, if they were to occur. For flares, facilities still must comply with the underlying combustion efficiency standards (*e.g.,* NHVcz) to ensure the flare is achieving the level of destruction efficiency required by the underlying MACT standards in the MON.

The comments about facilities continuously installing redundant PRDs or closing up PRDs and opening new ones to be able to have as many PRD events as possible without violating the PRD work practice are hypothetical and the EPA has no information to support such a strategy. In addition, MON facilities must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions, and setting up such a strategy would be inconsistent with the General Duty requirements of 40 CFR 63.2450(u). Also, the part 63 General Provisions contain a circumvention provision at 40 CFR 63.4(b) that states in part that ''no owner or operator subject to the provisions of this part shall build, erect, install, or use any article, machine, equipment, or process to conceal an emission that

would otherwise constitute noncompliance with a relevant standard.'' Thus, a source that took such hypothetical actions as the commenter suggests would be open to an enforcement action for violating the circumvention provision.

The commenter opposed the PRD work practice and provided additional information about PRD releases from Petroleum Refineries. Much of what was provided by the commenter is irrelevant to the final PRD work practice or is insufficient for the Agency to use to update the work practice standards we are finalizing for PRDs at MON facilities. The EPA notes that the PRDs at Petroleum Refineries are already subject to the work practice standards we are finalizing in this action. In setting the refineries work practice, the EPA conducted a Monte Carlo analysis spanning 20 years. Given that the Agency lacks specific PRD release information and smoking flare information for MON sources, we stated in our technology review memorandum at proposal that we would consider information from other source categories like Petroleum Refineries and Ethylene Production facilities when determining what is achievable for the best performing sources in the Miscellaneous Organic Chemical Manufacturing source category and we made reasonable estimates where needed for estimated cost impacts of implementing the work practice standards we are finalizing for these sources. If anything, the refinery compliance report data provided by the commenter show that the work practice standards we finalized for Petroleum Refineries are quite effective at minimizing PRD releases to the atmosphere and should translate to being effective at minimizing emissions from PRD releases at MON facilities as well. As the commenter stated, among the 998 uncontrolled PRDs reported in the compliance reports that were reviewed from calendar year 2019, there was only one three-minute release to the atmosphere.

Comment: One commenter disagreed with requiring a root cause analysis and corrective action in every situation in which a PRD releases to the atmosphere. The commenter noted that under the Chemical Accident Prevention Program, an incident investigation with root cause analysis is required only when the release was a catastrophic release or could reasonably have resulted in a catastrophic release. The commenter added that the EPA has not established sufficient evidence to indicate that a root cause analysis is being performed by the best performing sources in the MON category routinely for all PRD releases regardless of whether they meet the definition of ''catastrophic release.''

Response: As previously mentioned in this section of this preamble, the work practice standard we are finalizing provides a comprehensive program to manage entire populations of PRDs, includes prevention measures, continuous monitoring, root cause analysis, and corrective actions, and addresses the potential for violations for multiple releases over a 3-year period. Implementing measures such as requiring root cause analysis and corrective action analysis will ensure that the work practice standards are effective and that the best PRD release management practices are followed so that the same events do not recur in the future. The commenter also does not provide any data to support their assertion that the best performers do not conduct a root cause/corrective analysis after a PRD release occurs. We followed the requirements of section 112 of the CAA, including CAA section 112(h), in establishing what work practice constituted the MACT standard for PRDs.

c. Degassing Storage Tanks

Comment: Several commenters requested that the EPA add a standard for minimizing emissions arising from degassing storage tanks that are complying with the control requirements in Table 4 to 40 CFR part 63, subpart FFFF. A commenter explained this request is due to their current interpretation of the proposed rule, wherein 40 CFR 63.6(e)(1) and 40 CFR 63.2450(a)(1) no longer applies, and thus facilities may be required to vent to control devices at all times, even during degassing events. A commenter stated that the current rule requires facilities to address minimization of emissions from shutdown, which includes degassing, in the SSM plan, and that facilities have historically considered degassing emissions from shutdown of storage tanks to be covered by their SSM plans per 40 CFR 63.6(e)(1) and 40 CFR 63.2450(a)(1) and relied on the language in 40 CFR 63.6(e)(1) and 40 CFR 63.2450(a)(1) that back-up control devices are not required. The commenter requested the EPA subcategorize storage vessel degassing emissions as maintenance vents based on class, just as the EPA proposed for process vents. The commenter contended that the Texas permit conditions presented in the memorandum, *Review of Regulatory Alternatives for Certain Vent Streams in the Ethylene Production Source Category,* available in the docket for this rulemaking, apply equally to both maintenance vents and degassing of storage tanks and stated these permit conditions reflect what the best performers have implemented for storage tank degassing (for both fixed and floating roofs) for both new and existing sources. According to the commenters, it is not feasible to control all the emissions from the entire storage tank emptying and degassing event, and at some point the storage tank must be opened and any remaining vapors vented to the atmosphere. The commenter further stated that this venting of vapors is similar to the EPA description for maintenance vents in the preamble to the proposed rule.

Another commenter recommended a work practice standard that would require emptying the storage vessel as much as practical allows; and if the storage vessel is required to be controlled in Table 4 to 40 CFR part 63, subpart FFFF, then it would be required to be degassed to a control device, fuel gas system, or process prior to opening to the atmosphere. The commenter also recommended that if the storage vessel is not required to be controlled in Table 4 to 40 CFR part 63, subpart FFFF, then it could be vented to atmosphere after removing as much liquid as practical.

Response: We agree with the commenters that complying with the storage tank requirements in Table 4 to 40 CFR part 63, subpart FFFF, is not appropriate during storage tank degassing events and a separate standard for storage tank degassing is necessary, due to the nature of the activity. With the removal of SSM requirements in this final rule, a standard specific to storage tank degassing does not exist when storage tanks are using control devices to comply with the requirements in Table 4 to 40 CFR part 63, subpart FFFF. We also agree with the commenters that storage tank degassing is similar to maintenance vents (*e.g.,* equipment openings) and that there must be a point in time when the storage tank can be opened and any emissions vented to the atmosphere. In response to this comment, we reviewed available data to determine how the best performers are controlling storage tank degassing emissions.

We are aware of three regulations regarding storage tank degassing, two in the state of Texas and the third for the SCAQMD in California. Texas has degassing provisions in the Texas Administrative Code (TAC) [23] and

[23] See 30 TAC Chapter 115, Subchapter F, Division 3, available at *https://texreg.sos.state.tx.us/public/readtac%24ext.ViewTAC?tac_view=5&ti=30&pt=1&ch=115&sch=F&div=3&rl=Y.*

through permit conditions (as noted by the commenter),[24] while Rule 1149 contains the SCAQMD degassing provisions.[25] The TAC requirements are the least stringent and require control of degassing emissions until the vapor space concentration is less than 35,000 ppmv as methane or 50 percent of the lower explosive limit (LEL). The Texas permit conditions require control of degassing emissions until the vapor space concentration is less than 10 percent of the LEL or until the VOC concentration is less than 10,000 ppmv, and SCAQMD Rule 1149 requires control of degassing emissions until the vapor space concentration is less than 5,000 ppmv as methane. The Texas permit conditions requiring compliance with 10 percent of the LEL and SCAQMD Rule 1149 control requirements are considered equivalent because 5,000 ppmv as methane equals 10 percent of the LEL for methane.

MON facilities located in Texas are subject to the permit conditions, but no MON facilities are subject to the SCAQMD rule. Of the 201 currently operating MON facilities, 39 are in Texas. Therefore, the Texas permit conditions relying on storage tank degassing until 10 percent of the LEL is achieved reflect what the best performers have implemented for storage tank degassing, and we considered this information as the MACT floor for both new and existing sources. Notably, this also aligns with the commenter's assessment.

We reviewed Texas permit condition 6 (applicable to floating roof storage tanks) and permit condition 7 (applicable to fixed roof storage tanks) for key information that could be implemented to form the basis of a standard for storage tank degassing. The Texas permit conditions require control of degassing emissions for floating roof and fixed roof storage tanks until the vapor space concentration is less than 10 percent of the LEL. The permit conditions also specify that facilities can also degas a storage tank until they meet a VOC concentration of 10,000 ppmv, but we do not consider 10,000 ppmv to be equivalent to or as stringent as the compliance option to meet 10 percent of the LEL and are not including this as a compliance option. We also do not expect the best performers would be using this concentration for compliance, which is supported by the commenters recommending the requirements mimic the maintenance vent requirements and because the Texas permit conditions allow facilities to calibrate their LEL monitor using methane. Storage tanks may be vented to the atmosphere once the storage tank degassing concentration threshold is met (*i.e.,* less than 10 percent of the LEL) and all standing liquid has been removed from the tank to the extent practicable. These requirements are considered MACT for both new and existing sources, and we are finalizing these requirements at 40 CFR 63.2470(f).

We calculated the impacts due to controlling storage tank degassing emissions by evaluating the population of storage tanks that are subject to control under Table 4 to 40 CFR part 63, subpart FFFF, and not located in Texas. Storage tanks in the Miscellaneous Organic Chemical Manufacturing source category in Texas would already be subject to the degassing requirements, and there would not be additional costs or emissions reductions for these facilities. We estimated there are an average of 9 storage tanks per facility, based on a 2003 memorandum on MON storage tanks, and applied that to the 162 MON facilities that are not located in Texas, resulting in 1,458 storage tanks newly applicable to tank degassing requirements. Based on a review of CAA section 114 survey responses for ethylene production facilities, most storage tanks are degassed an average of once every 14 years. Using this average and the population of storage tanks that are not in Texas, we estimated 104 storage tank degassing events would be newly subject to control each year. Controlling storage tank degassing would reduce HAP emissions by 86 tons per year, with a total annual cost of approximately $489,000. See the technical memorandum, *Storage Tank Degassing Cost and Emissions Impacts for the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which is available in the docket for this rulemaking, for details on the assumptions and methodologies used in this analysis.

We also considered options beyond-the-floor, but we did not identify and are not aware of storage tank degassing control provisions more stringent than those discussed above and being finalized in this rule; therefore, no beyond-the-floor option was evaluated.

The remaining comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

4. What is the rationale for our final approach and final decisions for the revisions pursuant to CAA section 112(d)(2) and (3)?

We evaluated all of the comments on the EPA's proposed amendments to revisions for flares used as APCDs, clarifications for periods of SSM and bypasses, including PRD releases, bypass lines on closed vent systems, maintenance activities, certain gaseous streams routed to a fuel gas system, and requirements for storage tank degassing activities. For the reasons explained in section IV.A of the proposal preamble (84 FR 69182, December 17, 2019), we find that the flare amendments are needed to ensure that flares used as APCDs achieve the required level of MACT control and meet 98-percent destruction efficiency at all times as well as to ensure that CAA section 112 standards apply at all times. Similarly, the clarifications for periods of SSM and bypasses, including PRD releases, bypass lines on closed vent systems, maintenance activities, certain gaseous streams routed to a fuel gas system, and standards associated with storage tank emptying and degassing events are needed to be consistent with *Sierra Club* v. *EPA, 551 F.3d* 1019 (D.C. Cir. 2008) to ensure that CAA section 112 standards apply at all times. More information and rationale concerning all the amendments we are finalizing pursuant to CAA sections 112(d)(2) and (3) is in the preamble to the proposed rule (84 FR 69182, December 17, 2019), in section IV.C.3 of this preamble, and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* which is available in the docket for this rulemaking. Therefore, we are finalizing the proposed provisions for flares (except that we are not finalizing the work practice standard for velocity exceedances for flares operating above their smokeless capacity), finalizing the proposed clarifications for periods of SSM and bypasses, including PRD releases, bypass lines on closed vent systems, maintenance activities, and certain gaseous streams routed to a fuel gas system, and finalizing standards for storage tank emptying and degassing events.

[24] See *https://www.tceq.texas.gov/assets/public/permitting/air/Guidance/NewSourceReview/mss/chem-mssdraftconditions.pdf.*

[25] See *http://www.aqmd.gov/docs/default-source/rule-book/reg-xi/rule-1149.pdf.*

D. Amendments Addressing Emissions During Periods of SSM

1. What amendments did we propose to address emissions during periods of SSM?

We proposed amendments to the MON standards to remove and revise provisions related to SSM that are not consistent with the requirement that the standards apply at all times. In a few instances, we are finalizing alternative standards for certain emission points (*i.e.,* emergency flaring, PRDs, maintenance activities, and tank degassing) to minimize emissions during periods of SSM to ensure a continuous CAA section 112 standard applies ''at all times,'' (see section IV.C of this preamble); however for the majority of emission points in the Miscellaneous Organic Chemical Manufacturing source category, we proposed eliminating the SSM exemptions and to have the MACT standards apply at all times. More information concerning the elimination of SSM provisions is in section IV.E.1 of the proposal preamble (84 FR 69182, December 17, 2019).

2. How did the SSM provisions change since proposal?

We are finalizing the SSM provisions as proposed (84 FR 69182, December 17, 2019) with only minor changes to sufficiently address the SSM exemption provisions from subparts referenced by the MON standards, and the removal of applicability of 40 CFR 63.6(f)(1) and (h)(1) that are directly impacted by the 2008 Court decision.

3. What key comments did we receive on the SSM revisions and what are our responses?

While we are finalizing some alternative standards in this final rule for certain emission points during periods of SSM to ensure a continuous CAA section 112 standard applies ''at all times,'' (see section IV.C of this preamble), we also proposed eliminating the SSM exemptions for the majority of emission points in the Miscellaneous Organic Chemical Manufacturing source category. This section provides comment summaries and responses for the key comments received regarding our proposed revisions. Other comment summaries and the EPA's responses for additional issues raised regarding these activities as well as issues raised regarding our proposed revisions can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

Comment: One commenter stated that the proposed malfunction standards for PRDs break with prior Agency policy regarding malfunctions and the use of case-by-case enforcement discretion to address malfunctions. The commenter stated that the agency has repeatedly explained why case-by-case evaluation of such issues is the only workable approach and has repeatedly finalized prohibitions on uncontrolled releases from PRDs that vent directly to the atmosphere, fully aware that allowing such releases without an emission limit is a malfunction exemption prohibited both by the CAA and the Court's decision in *Sierra Club.* The commenter objected to this change and contended that the EPA did not clearly explain this break with prior precedent. The commenter noted that the EPA finalized similar provisions prohibiting PRD releases in MACT standards for Group IV Polymers and Resins, Pesticide Active Ingredient Manufacturing, and Polyether Polyols Production. The commenter further stated that the Court recently upheld this type of prohibition in *Mexichem Specialty Resins, Inc. v EPA,* 787 F.3d 544, 560–61 (D.C. Cir. 2015) and urged the EPA to finalize the standards for PRD as proposed. The commenter noted that in light of the EPA's prior policy, prohibiting uncontrolled PRD releases is lawful and consistent with the CAA. The commenter stated that the EPA has neither provided a reasoned explanation for the exemptions nor acknowledged or explained the break in its prior policy against malfunction exemptions.

Furthermore, the commenter observed that uncontrolled PRD releases are preventable and avoidable and that they need not occur if a facility avoids over-pressure in the system. The commenter referred to the proposal preamble, noting that such ''pressure build-ups are typically a sign of a malfunction of the underlying equipment,'' and PRDs ''are equipment installed specifically to release during malfunctions.'' Therefore, the commenter argued that the EPA cannot rely on any argument that equipment can fail, that PRDs are necessary to address over-pressure and avoid a larger safety incident, and that the EPA has not relied on or demonstrated with any evidence that it is a valid concern. The commenter stated that even if it may be considered by the EPA in an administrative enforcement context or by the courts in an enforcement case, the EPA cannot authorize, up front, a whole set of problematic releases.

The commenter argued that it would create a far stronger incentive to reduce smoking flares and uncontrolled PRD releases if the EPA simply recognized that such uncontrolled releases are prohibited and the flare requirements must apply at all times; treating one or two exceedances as a non-violation dramatically reduces the incentive for facilities to comply with the work practice standards.

The commenter also noted that the civil penalties available for such violations could provide some remedy for the air pollution a facility released, even if it were completely out of the facility's control. For example, the commenter stated that penalties won by a citizen suit may either go into a special fund ''to finance air compliance and enforcement activities'' that may help to address some part of the pollution or ''be used in beneficial mitigation projects which . . . enhance the public health or the environment.''

Other commenters agreed that the EPA has the authority and obligation to adopt work practice standards under the *Sierra Club* SSM decision. The commenters reiterated the *Sierra Club* decision and said the EPA must ensure that some ''emission standard'' applies at all times—except that the standard that applies during normal operation need not be the same standard for SSM periods. The commenters said the requirement for ''continuous'' standards means only that a facility may not install control equipment and then turn it off when atmospheric conditions are good; it does not mean that work practice standards must physically restrict emissions from all equipment at all times. The commenters said that the EPA has consistently imposed as ''MACT'' standards a variety of work practice obligations that do not prohibit or limit emissions to a specified level at all times but rather are designed to limit overall emissions from various processes over the course of a year. The commenters said the EPA's own LDAR programs illustrate this distinction. The commenters contended that no court has suggested that periods of ''unlimited emissions'' [*e.g.,* 40 CFR 63.119(b)(1) (internal floating roof allowed not to contact with stored material during filling/emptying); 40 CFR 63.119(b)(6) (covers on tank openings may be opened when needed for access to contents); 40 CFR 63.135(c)(2) (allowing openings on containers as necessary to prevent physical damage)] render these requirements insufficient under CAA section 112. Rather, the commenters said that work practice standards associated with these requirements—*e.g.,* maintaining openings in a closed

position except as necessary for access; conducting filling/emptying as rapidly as possible—are considered to be acceptable mechanisms to minimize overall emissions from these types of equipment, even when they do not limit emissions at all during a few brief periods that are necessary for operational or safety reasons.

Response: We disagree with the comment that the work practice standards that we are finalizing for PRD releases and for emergency releases from flares are malfunction exemptions and we disagree with the assertion that the standards do not apply at all times. We also disagree that PRDs are simply bypasses for emissions that are subject to emission limits and controls or that they allow for uncontrolled emissions without violation or penalty. We also disagree that the standards being finalized allow facilities to ignore the flare tip velocity and no-visible emissions flare requirements such that a flare can smoke without repercussions and without limits repeatedly.

As discussed in section IV.C of this preamble, the requirements and work practice standards require a number of prevention measures that operators must undertake to prevent PRD release and flare smoking events, including the installation and operation of continuous monitoring device(s) to identify when a PRD release has occurred. The work practice combustion efficiency standards (specifically limits on the NHVcz) and requirements to have a continuously lit pilot flame or flare flame apply at all times, including during periods of emergency flaring. We also note that a flare is not a specific emission source within the MON standards; rather, a flare is an APCD that has always been a type of emission control technology that miscellaneous organic chemical manufacturing facilities could utilize to comply with the underlying MACT standards. Flares are associated with a wide variety of process equipment, and the emissions routed to a flare during a malfunction can vary widely based on the cause of the malfunction and the type of associated equipment. As such, there can be certain instances when flares may be operated above their smokeless capacity to control emissions from certain events such as malfunction events, and we are finalizing work practice standards for visible emissions events when flares are operated above their smokeless capacity based on the best performing flares in the source category.

Further, we are limiting the number of releases that would result in a deviation from the work practice standards. Regarding the comment that civil penalties may provide remedy for these releases, we note that the work practice standards provide for sufficient specificity to identify when a release is a deviation from the work practice standard, as well as a root cause analysis to help guide a decisionmaker in deciding whether to pursue an enforcement action because they believe a violation has occurred and for a court or other arbiter to rule on any claim.

4. What is the rationale for our final approach and final decisions to address emissions during periods of SSM?

We evaluated all of the comments on the EPA's proposed amendments to the SSM provisions. For the reasons explained in the proposed rule (84 FR 69182, December 17, 2019), we determined that these amendments, which remove and revise provisions related to SSM, are necessary to be consistent with the requirement that the standards apply at all times. More information concerning the amendments we are finalizing for SSM is in the preamble to the proposed rule and in the comments and our specific responses to the comments in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking. Therefore, we are finalizing our approach for the SSM provisions as proposed.

E. Other Amendments to the MACT Standards

1. What other amendments did we propose for the Miscellaneous Organic Chemical Manufacturing source category?

We proposed adding monitoring requirements at 40 CFR 63.2450(e)(7) for adsorbers that cannot be regenerated and regenerative adsorbers that are regenerated offsite because the MON does not currently include specific monitoring requirements for this type of APCD. We proposed that owners or operators of this type of APCD use dual adsorbent beds in series and conduct daily monitoring. In order to monitor performance deterioration, we proposed daily measurements of HAP or TOC using a portable analyzer or chromatographic analysis for non-regenerative adsorbers (to be taken daily on the outlet of the first adsorber bed in series using a sample port). Furthermore, in order to relieve some monitoring burden, we proposed an option to reduce the frequency of monitoring with the portable analyzer from daily to weekly or monthly.

We also proposed that owners or operators submit electronic copies of required flare management plans (at 40 CFR 63.2450(e)(5)(iv)), compliance reports (at 40 CFR 63.2520(e)), performance test reports (at 40 CFR 63.2520(f)), and performance evaluation reports (at 40 CFR 63.2520(g)) through the EPA's CDX using CEDRI, and we proposed two narrow circumstances in which owners or operators may seek extensions to the deadline if they are prevented from reporting by conditions outside of their control within five business days of the reporting deadline. We proposed at 40 CFR 63.2520(h) that an extension may be warranted due to outages of the EPA's CDX or CEDRI that precludes an owner or operator from accessing the system and submitting required reports. We also proposed at 40 CFR 63.2520(i) that an extension may be warranted due to a *force majeure* event, such as an act of nature, act of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

Finally, we proposed revisions to clarify text or correct typographical errors, grammatical errors, and cross-reference errors. These editorial corrections and clarifications are summarized in Table 11 of the proposal preamble. See 84 FR 69228, December 17, 2019.

2. How did the other amendments for the Miscellaneous Organic Chemical Manufacturing source category change since proposal?

We are finalizing the other amendments discussed in section IV.E.1 of this preamble as proposed, except that, in the final rule, we are correcting an error to clarify that compliance reports must be submitted electronically (*i.e.,* through the EPA's CDX using the appropriate electronic report template for this subpart) beginning three years after date of publication of final rule in the **Federal Register** or once the reporting template has been available on the CEDRI website for 1 year, whichever date is later. Also, as discussed further in the response to comment document for this rulemaking, we are adding back in provisions originating from 40 CFR 63.104(a)(1), (2), (5), and (6) that were inadvertently removed in the proposed rule. Finally, we are including several additional minor clarifying edits in the final rule based on comments received during the public comment period.

We are revising the proposed monitoring requirements at 40 CFR 63.2450(e)(7) for adsorbers that cannot be regenerated and regenerative

adsorbers that are regenerated offsite to reduce the frequency of monitoring with the portable analyzer based upon the design life of the bed. Instead of daily monitoring, the final rule will allow owners or operators to monitor monthly if the bed has at least two months of the bed design life remaining and weekly if the bed has between two months and two weeks of bed design life remaining. Daily monitoring is required once the bed has less than two weeks of bed design life remaining. Under the final rule, owners or operators will also be required to conduct monitoring no later than 3 days after a bed is put into service as the first bed to confirm that it is functioning properly.

3. What key comments did we receive on the other amendments for the Miscellaneous Organic Chemical Manufacturing source category and what are our responses?

This section provides comment and responses for the key comments received regarding our proposed revisions to the monitoring requirements for adsorbers that cannot be regenerated and regenerative adsorbers that are regenerated offsite. With the exception of these comments related to the proposed monitoring requirements for adsorbers, we did not receive many substantive comments on the other amendments in the MON RTR proposal. The comments we received regarding other amendments generally include issues related to electronic reporting, removal of certain exemptions for heat exchange systems, overlap provisions for equipment leaks, and revisions that we proposed for clarifying text or correcting typographical errors, grammatical errors, and cross-reference errors. The comments and our specific responses to these issues can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

Comment: Several commenters disagreed with the proposed requirement at 40 CFR 63.2450(e)(7) for adsorbers that cannot be regenerated or adsorbers that are regenerated offsite.

Commenters contended that requiring the addition of a second adsorber bed in series is not a monitoring function but is a change in allowed controls and, therefore, is an equipment standard that must be evaluated under CAA section 112(d)(6).

Commenters disagreed with the EPA's justification for requiring a dual bed system as ''use of a single bed does not ensure continuous compliance unless the bed is replaced significantly before breakthrough,'' (84 FR 69227) arguing that (1) This same argument also applies to dual bed systems, and (2) the EPA makes no claim that use of a single bed is not achieving continuous compliance frequently enough to justify disallowing single bed systems. Commenters stated that facilities typically follow conservative single-bed change procedures (*e.g.,* 20 to 30 percent of bed saturation) and that single beds are typically oversized and used where only a small percentage of their capacity is expected to be needed. Commenters asserted that conservative single bed change decisions reduce the monitoring required in such cases under applicable rules or permits, or a very conservative breakthrough point is set by rule or permit. Commenter noted that if owners or operators replace single beds prematurely and the cost of the replacement bed is small compared to the increased compliance assurance, then early replacement should be the preferred approach for assuring compliance, because it avoids all of the costs and emissions associated with having dual beds and results in a larger margin of compliance assurance than for a dual bed installation.

Commenter claimed that adding piping components required for a dual bed system will have negative consequences: (1) Adding continuous fugitive emissions from the additional valves and connectors, and (2) creating, in some cases, operating concerns or requiring addition of compression due to the added back pressure from the second bed.

Commenters contended that the proposed equipment standard is not cost effective and would not achieve any reduction in emissions. Commenters disagreed with the EPA's position that there would be no cost for a second bed in a dual bed system and argued that the EPA did not consider the cost of design and engineering, additional structural elements and foundations, reconfiguring the piping, adding valves to isolate each bed, and relocating existing single beds where space is not available for a second bed.

Commenters recommended that the EPA not require dual adsorber beds and monitoring for temporary adsorbers (*e.g.,* systems used for less than 6 months) and small adsorbers that infrequently need replacement. Commenters stated that the only requirement for such systems should be a record demonstrating the bed life is appropriate for the maximum expected emissions loading. Commenter recommended that small adsorbers that are operated solely as back-up control devices should also be exempted on the basis of the requirements not being cost effective, and on the basis that they are operated no more than some percentage of the minimum potential saturation time.

Commenters asserted that 3 years would be needed to comply with this proposed requirement because the retrofit of an existing single bed system will have to be engineered, appropriated, and then designed and constructed.

Commenters requested that, if the EPA promulgates the adsorber monitoring requirements, the EPA should also remove the requirement at 40 CFR 63.2450(e)(7)(iii)(B) to conduct daily monitoring for the first three adsorber bed change outs because this amount of testing is excessive and represents an unnecessary cost. Commenters stated that, to ensure compliance, some facilities routinely replace adsorbent well in advance of breakthrough. For example, on a non-continuous/intermittent backup system, commenters stated that some facilities replace adsorbent on a yearly basis, regardless of whether the bed is approaching saturation, and bed life would never be established as proposed. In other cases, commenters stated that bed life may be several months, and daily monitoring would be unnecessarily expensive. Commenters recommended that the EPA adopt a reduced monitoring frequency similar to the Benzene Waste Operations NESHAP at 40 CFR 61.354(d) where facilities are allowed to monitor either daily or at intervals no greater than 20 percent of the design carbon replacement interval.

Commenters also requested the use of colorimetric tubes to monitor for breakthrough in place of instrument monitoring. These tubes are placed in a fitting in the vent at the outlet of the first adsorber bed and are filled with a reagent that changes color when exposed to specific target compounds or to volatile organic compounds, depending on the vapor, which indicates breakthrough.

Finally, commenters requested that the EPA clarify that systems with more than two adsorber beds in series would be allowed and that dual bed (*i.e.,* two bed) systems are not the only ones allowed.

Response: The EPA is revising the proposed monitoring requirements for non-regenerative adsorbers to address some of the commenters concerns, but the final rule still requires the use of a dual bed system in series and monitoring at the outlet of the first bed to detect breakthrough.

The EPA acknowledges that the proposed requirements could have been considered under CAA section 112(d)(6) because of the specification to have two adsorber beds in series, instead of as a proposed change to the monitoring requirements. However, the EPA presented the technical rationale for why a second bed was needed and for why the estimated costs for adding a second bed would be minimal. This rationale would not have been any different if the EPA described the proposed changes under CAA section 112(d)(6) instead of as a monitoring change. These changes were proposed because the current 40 CFR part 63, subpart FFFF, contained no monitoring requirements for non-regenerative adsorbers.

The commenters requested that the EPA establish work practice or operational standards that would allow the continued use of a single bed system (*e.g.,* changing adsorber beds when they had reached some percentage of their designed capacity). While we agree with the comment that a single bed approach can be very effective at controlling HAP from sources subject to the MON, our goal is to ensure that sources are complying with the standards at all times and even a well maintained single bed system is vulnerable to errors that are not possible with the dual bed system we are requiring. The proposed and final monitoring requirements for non-regenerative adsorbers fulfill the EPA's obligation to establish monitoring requirements to ensure continuous compliance with the emission limits (*e.g.,* 98-percent control or a 20 ppm TOC outlet concentration) when owners or operators are using these types of control devices to comply with the standards.

In response to the commenters' concerns about the costs of adding a second adsorber bed, we used the EPA's cost algorithms to estimate the cost of a second carbon adsorber bed for two adsorber scenarios. In the first, scenario, the EPA estimated the cost of a replaceable-canister type adsorber holding 180 lbs of carbon. The total capital investment of the second bed (including installation and auxiliary equipment) is about $5,100, and the total annual cost is about $900. In the second scenario, we estimated the cost of an adsorber that holds 3,000 lbs of carbon and in which the carbon is removed and replaced by fresh carbon when needed. The total capital investment of the second bed (including installation and auxiliary equipment) is about $22,300, and the total annual cost is about $3,000. We assumed no additional labor would be required for operation and maintenance of the second adsorber bed compared to operating and maintaining a single bed adsorber. We documented this analysis for the final rulemaking in the memorandum, *Analysis of Monitoring Costs and Dual Bed Costs for Non-Regenerative Carbon Adsorbers Used in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which is available in the docket for this rulemaking.

In both scenarios, we assumed that the first bed would be replaced when it reached breakthrough (*i.e.,* its equilibrium capacity, which is when the adsorption zone of the bed reaches the bed outlet and the volatile concentration in the exhaust begins to rise) based on monitoring at the outlet of the first bed. At that time, the owner or operator would divert the flow from the first to the second bed, the canisters or carbon would be replaced in the first bed, and it would then be returned to service as the second bed in the series. We did not include the cost of replacing the canisters or the carbon in the annual costs because the amount of carbon used would not increase as a result of using a second bed in series. The EPA still concludes that having two beds in series and performing monitoring at the outlet of the first bed will reduce the amount of adsorber media (*e.g.,* activated carbon) used by facilities because they will not have to replace the adsorber media until it reaches equilibrium capacity. With only a single bed and no monitoring, facilities need to replace the adsorber media more frequently based on the estimated working capacity of the bed (which is a fraction of the equilibrium capacity) so as to maintain compliance and to avoid exceeding outlet concentration limits. The EPA determined at proposal that the use of two beds in series and the use of monitoring will maximize the life of each bed and reduce adsorber media replacement costs. The EPA has not changed that determination based on the public comments submitted or on the analyses completed since proposal.

The EPA is revising the proposed monitoring requirements to reduce the frequency of monitoring. In the final rule, owners or operators will be able to conduct monitoring based on the design life of the adsorber bed. The final monitoring requirements are similar to what the EPA proposed for owners or operators who establish the life of the adsorber bed based on at least three bed replacement cycles. However, in the final rule, the EPA will allow owners or operators to use the design life of the bed and to monitor monthly if the bed has at least two months of the bed design life remaining and weekly if the bed has between two months and two weeks of bed design life remaining. Once the remaining bed design life reaches two weeks, daily monitoring is required. This change from proposal will not lead to an increase in emissions because the final rule will still require the use of beds in series, and any emissions detected when the first bed reaches breakthrough will still be captured by the second bed in the series. After breakthrough on the first bed is detected, the first bed will be removed from service and replaced. The second bed will be moved to the first bed position and the newly replaced bed will become the second bed in series. Therefore, the newest bed will always be operated as a backup to the older bed. Under the final rule, owners or operators will also be required to conduct monitoring no later than 3 days after a bed is put into service as the first bed to confirm that it is functioning properly. This change will substantially reduce the cost of monitoring. For example, the capital cost of portable FID was estimated to be $9,000, and the total annual cost for daily monitoring was estimated to be $13,000, but the total annual cost for monthly and weekly monitoring were estimated to be $2,600 and $3,700, respectively.

We did not estimate the cost effectiveness (*i.e.,* the cost per ton of HAP reduced) of requiring the second adsorber bed and the final monitoring requirements because the second bed is acting as a backup to the first bed to capture any potential breakthrough, and it is difficult to estimate the mass of HAP that will be captured and the excess emissions that will be avoided by the monitoring.

The EPA is not including an exemption from the final rule requirements for adsorbers used for temporary applications or as backup for other control devices. Control devices used to comply with an emission limitation, even on a temporary basis, must still meet the same performance and monitoring requirements as one used on a permanent basis.

In the final rule, the EPA is not allowing the use of colorimetric tubes in place of instrument monitoring at the outlet of the first adsorber bed. The EPA investigated the use of these tubes but could not find any specification or quality assurance standard that could be incorporated by reference to ensure the accuracy of these tubes in detecting breakthrough. Additionally, we could not find information on the material contained within the tubes and whether the material would react with all HAP being controlled by adsorbers in the

Miscellaneous Organic Chemical Manufacturing source category.

Finally, the EPA is clarifying in the final rule, in response to comments, that systems with at least two beds are required, but systems with more than two beds in series are allowed.

4. What is the rationale for our final approach and final decisions for the other amendments for the Miscellaneous Organic Chemical Manufacturing source category?

Based on the comments received for these other amendments, we are generally finalizing all proposed requirements, with the exception of the monitoring requirements for adsorbers that cannot be regenerated or adsorbers that are regenerated offsite. For the reasons described in section IV.E.3 of this preamble, we are revising the proposed monitoring requirements for these adsorbers in the final rule to reduce the monitoring frequency from what we proposed.

In a few instances (*e.g.,* overlap provisions for equipment leaks), we received comments that led to additional minor editorial corrections and technical clarifications being made in the final rule, and our rationale for these corrections and technical clarifications can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing,* available in the docket for this rulemaking.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

We estimate that, as of November 6, 2018, there were 201 MON facilities. A complete list of known MON facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011).

B. What are the air quality impacts?

At the current level of control prior to the amendments being finalized in this action, the EPA estimates that ethylene oxide emissions were approximately 1.1 tpy (actuals) and 3.1 tpy (allowables) from the eight MON facilities with emission process groups (*i.e.,* process vents, storage tanks, equipment leaks) in ethylene oxide service. At the level of control required by the amendments being finalized in this action, which includes amendments to process vents, storage tanks, and equipment in ethylene oxide service (equipment leak Control Option 1), we estimated ethylene oxide emissions reductions of 0.76 tpy (actuals) and 2.7 tpy (allowables) for the source category.

At the level of control prior to the amendments being finalized in this action, we estimated HAP emissions for all MON facilities of approximately 7,420 tpy and VOC emissions of approximately 19,720 tpy, based on emissions from the MON modeling file available for 194 of the 201 MON facilities identified in this rulemaking. Note that seven of the 201 MON facilities did not report HAP emissions to the 2014 NEI for MON processes. Of this total, approximately 2,558 tpy of HAP and 6,730 tpy of VOC are attributed to emission process groups with amendments being finalized in this action. At the level of control required by the amendments being finalized in this action, we estimate HAP emissions reductions between 107 tpy and 130 tpy and VOC emissions reductions between 283 tpy and 532 tpy. As discussed in the proposal preamble (84 FR 69182, December 17, 2019), we estimated HAP emissions using two different methods (*i.e.,* based on the MON emission inventory and based on model plants, respectively), so estimated emission reductions are presented as a range. We also estimate excess emissions reductions from flares that could result from the final monitoring requirements, which we estimate to be 263 tpy HAP and 1,254 tpy VOC. When considering the flare excess emissions, the total emissions reductions as a result of the final amendments are estimated to be between 370 and 393 tpy of HAP and between 1,537 and 1,786 tpy of VOC. These emissions reductions are documented in the following memoranda, which are available in the docket for this rulemaking: *Clean Air Act Section 112(d)(6) Technology Review for Equipment Leaks Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule, Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule, Analysis of Control Options for Storage Tanks and Process Vents Emitting Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule, Analysis of Control Options for Equipment Leaks at Processes that use Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule, Control Option Impacts for Flares Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* and *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule.*

C. What are the cost impacts?

The total capital investment cost of the final amendments and standards is estimated at approximately $43 million, including approximately $40 million for MON facilities without ethylene oxide controls and $3 million from MON facilities with ethylene oxide controls. We estimate total annual costs of the final amendments, without recovery credits, to be approximately $13 million.

The nationwide costs of the amendments being finalized in this action are presented in Table 5 of this preamble for (1) All MON sources, (2) only MON sources not expected to be affected by the ethylene oxide-specific controls being finalized in this action (*i.e.,* equipment leaks, heat exchange systems, flares, PRDs, maintenance vents, storage tank degassing activities, recordkeeping and reporting), and (3) only MON sources expected to be affected by the ethylene oxide controls being finalized in this action (*i.e.,* storage tanks, process vents, equipment leaks). As described in this preamble, for ethylene oxide sources, we are finalizing amendments for storage tanks and process vents in ethylene oxide service. For equipment in ethylene oxide service, of the two co-proposed options we are finalizing equipment leak co-proposed Control Option 1, which requires that the same equipment leak standards (*i.e.,* lower the leak definition for batch pumps to 1,000 ppm and require connector monitoring at a leak definition of 500 ppm) will apply to all facilities in ethylene oxide service. These costs are presented in Table 5 of this preamble. There are 201 facilities affected by the amendments, and the number of facilities affected by each of the specific amendments is indicated in Table 5 below. The facility list was developed using methods described in section II.C of the proposal preamble (84 FR 69182, December 17, 2019). A complete list of known MON facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* which is

available in the docket for this rulemaking.

TABLE 5—TOTAL CAPITAL INVESTMENT AND TOTAL ANNUAL COSTS

[2016$]

	Number of facilities w/costs associated with new requirements	Total capital investment	Total annual costs w/o recovery credits	Total annual costs w/recovery credits
All MON Sources—Total	.....	42,700,000	12,700,000	12,300,000
MON Sources w/o Ethylene Oxide Controls—Total	.....	39,700,000	11,400,000	11,100,000
Flares [1]	21	17,200,000	4,090,000	4,090,000
Equipment Leaks [2]	193	829,000	150,000	81,800
PRDs [3]	201	18,700,000	4,770,000	4,770,000
Maintenance Vents [3]	201	.....	2,340	2,340
Heat Exchange Systems [4]	201	1,480,000	261,000	(14,300)
Degassing Tanks [5]	162	.....	489,000	489,000
Recordkeeping and Reporting	201	1,490,000	1,650,000	1,650,000
MON Sources w/Ethylene Oxide Controls—Total	.....	2,990,000	1,250,000	1,250,000
Equipment Leaks [6]	7	71,100	47,500	44,600
Process Vents [7]	3	2,740,000	943,000	943,000
Storage Tanks [7]	3	178,000	258,000	258,000

Costs are rounded to three significant figures.

[1] The flare costs include purchasing analyzers, monitors, natural gas and steam, developing a flare management plan, and performing root cause analysis and corrective action, and are discussed in the memorandum, *Control Option Impacts for Flares Located in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0006).

[2] Equipment leak costs include LDAR at a leak definition of 1,000 ppmv for light liquid pumps at batch processes, and are discussed in the memoranda, *Clean Air Act Section 112(d)(6) Technology Review for Equipment Leaks Located in the Miscellaneous Organic Chemical Manufacturing Source Category* (see Docket Item No. EPA–HQ–OAR–2018–0746–0003) and *Clean Air Act Section 112(d)(6) Technology Review for Equipment Leaks Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule* which are available in the docket for this rulemaking.

[3] PRD costs were developed to comply with the work practice standard being finalized in this action and include implementation of three prevention measures, performing root cause analysis and corrective action, and purchasing PRD monitors. Maintenance costs were estimated to document equipment opening procedures and circumstances under which the alternative maintenance vent limit is used. Costs are discussed in the memorandum, *Review of Regulatory Alternatives for Certain Vent Streams in the Miscellaneous Organic Chemical Manufacturing Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0010).

[4] Heat exchange systems costs include the use of the Modified El Paso Method to monitor for leaks, and are discussed in the memoranda, *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems Located in the Miscellaneous Organic Chemical Manufacturing Source Category* (see Docket Item No. EPA–HQ–OAR–2018–0746–0007) and *Clean Air Act Section 112(d)(6) Technology Review for Heat Exchange Systems in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which are available in the docket for this rulemaking.

[5] Costs for degassing storage tanks are discussed in the memorandum, *Storage Tank Degassing Cost and Emissions Impacts for the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which is available in the docket for this rulemaking.

[6] Equipment leak costs for equipment in ethylene oxide service include costs for equipment leak co-proposed Control Option 1. Control Option 1 includes LDAR at a leak definition of 1,000 ppmv for light liquid pumps at batch processes with monthly monitoring and connector monitoring at a leak definition of 500 ppmv with annual monitoring. Costs are discussed in the memoranda, *Analysis of Control Options for Equipment Leaks at Processes that use Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category* (see Docket Item No. EPA–HQ–OAR–2018–0746–0004) and *Analysis of Control Options for Equipment Leaks at Processes that use Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which are available in the docket for this rulemaking.

[7] Costs for process vents and storage tanks in ethylene oxide service include the requirement to control all storage tanks in ethylene oxide service, the installation of a control device that achieves 99.9-percent ethylene oxide emissions reductions, and initial and periodic performance testing of the control device, and are discussed in the memoranda, *Analysis of Control Options for Storage Tanks and Process Vents Emitting Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category* (see Docket Item No. EPA–HQ–OAR–2018–0746–0005) and *Analysis of Control Options for Storage Tanks and Process Vents Emitting Ethylene Oxide Located in the Miscellaneous Organic Chemical Manufacturing Source Category For the Final Rule,* which are available in the docket for this rulemaking.

D. What are the economic impacts?

The economic impact analysis is designed to inform decision makers about the potential economic consequences of the compliance costs outlined in section V.C of this preamble. The EPA performed a screening analysis for impacts on all affected facilities by comparing compliance costs to revenues at the ultimate parent company level. This is known as the cost-to-revenue or cost-to-sales test, or the ''sales test.'' The ''sales test'' is an impact methodology the EPA employs in analyzing entity impacts as opposed to a ''profits test,'' in which annualized compliance costs are calculated as a share of profits. The use of a sales test for estimating small business impacts for a rulemaking is consistent with guidance offered by the EPA on compliance with the Regulatory Flexibility Act (RFA) and is consistent with guidance published by the U.S. Small Business Administration's Office of Advocacy that suggests that cost as a percentage of total revenues is a metric for evaluating cost increases on small entities in relation to increases on large entities.

There are 201 MON facilities, owned by 99 parent companies, affected by the final amendments. Of the parent companies, 17 companies, or 17

percent, are small entities. We identified the North American Industry Classification System (NAICS) code for all parent companies and applied the U.S. Small Business Administration's table of size standards to determine which of the companies were small entities. Also, we calculated the cost-to-sales ratios for all the affected entities to determine (1) The magnitude of the costs of the amendments being finalized in this action and (2) whether there would be a significant impact on small entities. To be conservative, we used facility-specific costs without recovery credits. For all firms, the average cost-to-sales ratio is approximately 0.06 percent; the median cost-to-sales ratio is less than 0.01 percent; and the maximum cost-to-sales ratio is approximately 0.97 percent. For large firms, the average cost-to-sales ratio is approximately 0.01 percent; the median cost-to-sales ratio is less than 0.01 percent; and the maximum cost-to-sales ratio is approximately 0.52 percent. For small firms, the average cost-to-sales ratio is approximately 0.30 percent, the median cost-to-sales ratio is 0.11 percent, and the maximum cost-to-sales ratio is 0.97 percent. The facility-specific costs for the 17 small firms ranged from $35,083 to $42,746 annually (2016$). The costs of the final action are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms.

More information and details of this analysis is provided in the memorandum, *Economic Impact and Small Business Screening Assessments for Final Amendments to the National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing,* which is available in the docket for this rulemaking.

E. What are the benefits?

The EPA did not monetize the benefits from the estimated emission reductions of HAP associated with this final action. The EPA currently does not have sufficient methods to monetize benefits associated with HAP, HAP reductions, and risk reductions for this rulemaking. However, we estimate that the final rule amendments would reduce HAP emissions by 107 tons per year and thus lower risk of adverse health effects in communities near facilities subject to the MON.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Miscellaneous Organic Chemical Manufacturing source category across different demographic groups within the populations living near facilities.

Our analysis of the demographics of the population with estimated risks greater than 1-in-1 million indicates potential disparities in risks between demographic groups, including the African American, Hispanic or Latino, Over 25 Without a High School Diploma, and Below the Poverty Level groups. In addition, the population living within 50 km of the MON facilities has a higher percentage of minority, lower income, and lower education people when compared to the nationwide percentages of those groups. However, acknowledging these potential disparities, the risks for the source category were determined to be acceptable after implementation of the controls required by the final amendments, and emissions reductions from the final amendments will benefit these groups the most.

The documentation for this decision is contained in section IV.A of this preamble, and the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Miscellaneous Organic Chemical Manufacturing Source Category Operations* dated November 27, 2018, which is available in the docket for this rulemaking.

As noted in section IV, the EPA reanalyzed risks using emission inventory updates from a CAA section 114 request and additional information received during the public comment period. Based on the revised risk results, the EPA also updated the demographic analysis. The revised demographic analysis indicated slight changes (ranging from 1–3%) in the population with estimated risks greater than 1-in-1 million for four demographic groups (African American, Hispanic or Latino, Below the Poverty Level, and Linguistic Isolation). However, the overall conclusions remain the same. The updated demographic analysis, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Miscellaneous Organic Chemical Manufacturing Source Category Operations* dated May 21, 2020, is available in the docket for this rulemaking.

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are summarized in section IV.A of this preamble and are further documented in the risk report, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0013).

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is a significant regulatory action that was submitted to Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is found in the memorandum *Economic Impact and Small Business Screening Assessments for Final Amendments to the National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing,* in the docket for this rulemaking.

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

This action is considered an Executive Order 13771 regulatory action. Details on the estimated costs of this final rule can be found in the EPA's analysis of the potential costs and benefits associated with this action discussed in section V of this preamble.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1969.09. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

We are finalizing amendments that change the reporting and recordkeeping requirements for several emission sources at MON facilities (*e.g.,* flares, heat exchangers, PRDs, storage tanks, and process vents). Specifically, we are finalizing, as proposed, a requirement that owners or operators of MON facilities submit electronic copies of notification of compliance status reports (being finalized at 40 CFR 63.2520(d)), compliance reports (being finalized at 40 CFR 63.2520(e)), performance test reports (being finalized at 40 CFR 63.2520(f)), and performance evaluation reports (being finalized at 40 CFR 63.2520(g)) through the EPA's CDX using the CEDRI. We are also requiring recordkeeping of each report and other records for storage tank degassing, flares, PRDs, process vents, storage tanks, heat exchangers, bypass lines, and maintenance vents (being finalized at 40 CFR 63.2470(f), and 40 CFR 63.2525(m) through (r)). The final amendments also remove the malfunction exemption and impose other revisions that affect reporting and recordkeeping.

This information will be collected to assure compliance with 40 CFR part 63, subpart FFFF. The total estimated burden and cost for reporting and recordkeeping due to these amendments are presented below and are not intended to be cumulative estimates that include the burden associated with the requirements of the existing 40 CFR part 63, subpart FFFF.

Respondents/affected entities: Owners or operators of MON facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart FFFF).

Estimated number of respondents: 201 (total).

Frequency of response: Semiannual or annual. Responses include notification of compliance status reports and semiannual compliance reports.

Total estimated burden: 12,219 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,642,730 (per year), includes $2,405,799 annualized capital and operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses according to the Small Business Administration's small business size standards. The Agency has determined that 17 of the 99 affected entities are small entities that may experience an impact of an average cost-to-sales ratio of approximately 0.30 percent. Details of this analysis are presented in the memorandum, *Economic Impact and Small Business Screening Assessments for Final Amendments to the National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing,* which is available in the docket for this rulemaking.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. None of the MON facilities that have been identified as being affected by this final action are owned or operated by tribal governments or located within tribal lands within a 10 mile radius. Thus, Executive Order 13175 does not apply to this action. We conducted an impact analysis using the latitude and longitude coordinates from the risk modeling input file to identify tribal lands within a 10 and 50 mile radius of MON facilities to determine potential air quality impacts on tribes. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, although there were no tribal lands located within a 10 mile radius of MON facilities, the EPA offered consultation with 14 tribes that were identified within a 50 mile radius of an affected facility, however, no tribal officials requested consultation. Additional details regarding the consultation letter and distribution list can be found in the memorandum, *MON RTR Consultation Letter,* which is available in the docket for this rulemaking. The EPA also participated on a phone call with the National Tribal Air Association on December 12, 2019, and presented an overview of the rulemaking.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.A of this preamble and further documented in the risk report, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The overall energy consumption and

economic impact of these final amendments is expected to be minimal for MON facilities and their parent companies (some of which are engaged in the energy sector) and, therefore, we do not expect any adverse effects on the supply, distribution, or use of energy as a result.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking involves technical standards. As discussed in the proposal preamble (84 FR 69182, December 17, 2019), the EPA conducted searches for the MACT standards through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 1A, 2, 2A, 2C, 2D, 2F, 2G, 3, 3A, 3B, 4, 5, 15, 18, 21, 22, 25, 25A, 25D, 26, 26A, and 29 of 40 CFR part 60, appendix A, 301, 305, 316, and 320 of 40 CFR part 63, 624 and 625 of 40 CFR part 136, appendix A, 1624, 1625, 1666 and 1671 of 40 CFR part 136, appendix A, 5030B (SW–846), 5031, 8260, 8260B (SW–846), 8260D (SW–846), 8270 and 8430 (SW–846) Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, EPA Publication SW–846 third edition. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA reviewed it as a potential equivalent method.

The EPA incorporates by reference VCS ASTM D5790–95 (Reapproved 2012), ''Standard Test Method for Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,'' as an acceptable alternative to EPA Method 624 (and for the analysis of total organic HAP in wastewater samples). For wastewater analyses, this ASTM method should be used with the sampling procedures of EPA Method 25D or an equivalent method to be a complete alternative. The ASTM standard is validated for all of the 21 volatile organic HAP (including toluene) targeted by EPA Method 624 but is also validated for an additional 14 HAP not targeted by the EPA method. This test method covers the identification and simultaneous measurement of purgeable volatile organic compounds. This method is applicable to a wide range of organic compounds that have sufficiently high volatility and low water solubility to be efficiently removed from water samples using purge and trap procedures. We note that because the Cellulose Products Manufacturing RTR proposed rule has already proposed to revise the performance test requirements table (Table 4 to subpart UUUU of part 63) to add IBR for ASTM D5790–95 (Reapproved 2012) (see 84 FR 47375, September 9, 2019), the EPA is not incorporating this specific aspect of this VCS by reference.

The EPA incorporates by reference VCS ASTM D6420–18, ''Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry'' as an acceptable alternative to EPA Method 18 with the following caveats. This ASTM procedure has been approved by the EPA as an alternative to EPA Method 18 only when the target compounds are all known and the target compounds are all listed in ASTM D6420–18 as measurable. ASTM D6420–18 should not be used for methane and ethane because the atomic mass is less than 35; and ASTM D6420–18 should never be specified as a total VOC method. The ASTM D6420–18 test method employs a direct interface gas chromatograph-mass spectrometer to measure 36 VOC. The test method provides on-site analysis of extracted, unconditioned, and unsaturated (at the instrument) gas samples from stationary sources.

The EPA incorporates by reference VCS ASTM D6784–02 (Reapproved 2008), ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method),'' as an acceptable alternative to EPA Method 101A of appendix B to 40 CFR part 61 and EPA Method 29 of appendix A–8 to 40 CFR part 60 (portion for mercury only) as a method for measuring mercury. Note that this applies to concentrations of approximately 0.5 to 100 micrograms per normal cubic meter of air. This method describes equipment and procedures for obtaining samples from effluent ducts and stacks, equipment and procedures for laboratory analysis, and procedures for calculating results. This method is applicable for sampling elemental, oxidized, and particle-bound mercury in flue gases of coal-fired stationary sources.

The three ASTM methods (ASTM D5790–95 (Reapproved 2012), ASTM D6420–18, and ASTM D6784–02 (Reapproved 2008)) are available at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *https://www.astm.org/.*

While the EPA identified 23 other VCS as being potentially applicable, the Agency decided not to use them because these methods are impractical as alternatives because of the lack of equivalency, documentation, validation date, and other important technical and policy considerations. The search and review results have been documented and are in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing NESHAP RTR,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0018).[26]

Under 40 CFR 63.7(f) and 40 CFR 63.8(f), subpart A—General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

Finally, although not considered a VCS, the EPA incorporates by reference, ''Purge-And-Trap For Aqueous Samples'' (SW–846–5030B), ''Volatile, Nonpurgeable, Water-Soluble Compounds by Azeotropic Distillation'' (SW–846–5031), and ''Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)'' (SW–846–8260D) into 40 CFR 63.2492(b) and (c)(1); and ''Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources,'' into 40 CFR 63.2490(d)(1)(iii)(A) and (B), and 40 CFR 63.2525(r)(4)(iv)(A). Each of these methods is used to identify organic HAP in water; however, SW–846–5031, SW–846–8260D, and SW–846–5030B use water sampling techniques and the Modified El Paso Method uses an air stripping sampling technique. The SW–846 methods are reasonably available from the EPA at *https://www.epa.gov/hw-sw846* while the Modified El Paso Method is reasonably available from TCEQ at *https://www.tceq.texas.gov/assets/public/compliance/field_ops/guidance/samplingappp.pdf.*

[26] At proposal, we identified two 40 CFR part 63, subpart SS, VCS (*i.e.,* ANSI/ASME PTC 19–10–1981–Part 10 and ASTM D6348–12e1) that were also identified in the NTTAA review for the Ethylene Production RTR, and these VCS have already been finalized as amendments in that action (for further information, see Docket ID No. EPA–HQ–OAR–2017–0357 and 84 FR 54329, October 9, 2019).

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

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

The documentation for this decision is contained in section IV.A of this preamble and in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Miscellaneous Organic Chemical Manufacturing Source Category Operations,* available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0013).

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, the EPA is amending 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by:
■ a. Revising paragraphs (h)(73), (94), and (102);
■ b. Redesignating paragraphs (n)(14) through (25) as paragraphs (n)(17) through (28) and paragraphs (n)(10) through (13) as paragraphs (n)(12) through (15);
■ c. Adding new paragraphs (n)(10), (11), and (16); and
■ d. Revising paragraph (t)(1).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(h) * * *

(73) ASTM D5790–95 (Reapproved 2012), Standard Test Method for Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry, Approved June 15, 2012, IBR approved for § 63.2485(h) and Table 4 to subpart UUUU.

* * * * *

(94) ASTM D6420–18, Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry, Approved November 1, 2018 IBR approved for §§ 63.987(b), 63.997(e), and 63.2354(b), table 5 to subpart EEEE, and § 63.2450(j).

* * * * *

(102) ASTM D6784–02 (Reapproved 2008), Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), (Approved April 1, 2008), IBR approved for §§ 63.2465(d), 63.11646(a), and 63.11647(a) and (d) and tables 1, 2, 5, 11, 12t, and 13 to subpart DDDDD, tables 4 and 5 to subpart JJJJJ, tables 4 and 6 to subpart KKKKK, table 4 to subpart JJJJJJ, table 5 to subpart UUUUU, and appendix A to subpart UUUUU.

* * * * *

(n) * * *

(10) SW–846–5030B, Purge-And-Trap For Aqueous Samples, Revision 2, December 1996, in EPA Publication No. SW–846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, IBR approved for § 63.2492(b) and (c).

(11) SW–846–5031, Volatile, Nonpurgeable, Water-Soluble Compounds by Azeotropic Distillation, Revision 0, December 1996, in EPA Publication No. SW–846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, IBR approved for § 63.2492(b) and (c).

* * * * *

(16) SW–846–8260D, Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry, Revision 4, June 2018, in EPA Publication No. SW–846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition, IBR approved for § 63.2492(b) and (c).

* * * * *

(t) * * *

(1) ''Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources,'' Revision Number One, dated January 2003, Sampling Procedures Manual, Appendix P: Cooling Tower Monitoring, January 31, 2003, IBR approved for §§ 63.654(c) and (g), 63.655(i), 63.1086(e), 63.1089, 63.2490(d), 63.2525(r), and 63.11920.

* * * * *

Subpart FFFF—National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing

■ 3. Section 63.2435 is amended by revising paragraph (c)(3) to read as follows:

§ 63.2435 Am I subject to the requirements in this subpart?

* * * * *

(c) * * *

(3) The affiliated operations located at an affected source under subparts GG (National Emission Standards for Aerospace Manufacturing and Rework Facilities), KK (National Emission Standards for the Printing and Publishing Industry), JJJJ (NESHAP: Paper and Other Web Coating), MMMM (NESHAP: Surface Coating of Miscellaneous Metal Parts and Products), and SSSS (NESHAP: Surface Coating of Metal Coil) of this part. Affiliated operations include, but are not limited to, mixing or dissolving of coating ingredients; coating mixing for viscosity adjustment, color tint or additive blending, or pH adjustment; cleaning of coating lines and coating line parts; handling and storage of coatings and solvent; and conveyance and treatment of wastewater.

* * * * *

■ 4. Section 63.2445 is amended by revising paragraphs (a) introductory text and (b) and adding paragraphs (g) through (i) to read as follows:

§ 63.2445 When do I have to comply with this subpart?

(a) Except as specified in paragraphs (g) through (i) of this section, if you have a new affected source, you must comply with this subpart according to the requirements in paragraphs (a)(1) and (2) of this section.

* * * * *

(b) Except as specified in paragraphs (g) through (i) of this section, if you have an existing source on November 10, 2003, you must comply with the requirements for existing sources in this subpart no later than May 10, 2008.

* * * * *

(g) All affected sources that commenced construction or reconstruction on or before December 17, 2019, must be in compliance with the requirements listed in paragraphs (g)(1) through (7) of this section upon

initial startup or on August 12, 2023, whichever is later. All affected sources that commenced construction or reconstruction after December 17, 2019, must be in compliance with the requirements listed in paragraphs (g)(1) through (7) of this section upon initial startup, or on August 12, 2020 whichever is later.

(1) The general requirements specified in §§ 63.2450(a)(2), (e)(4) through (7), (g)(6) and (7), (i)(3), (j)(5)(ii), (j)(6), (k)(1)(ii), (k)(7) and (8), (t), and (u), 63.2520(d)(3) and (e)(11) through (13), 63.2525(m) through (o), and 63.2535(m).

(2) For process vents, the requirements specified in §§ 63.2450(v), 63.2520(e)(14), and 63.2525(p).

(3) For storage tank degassing, the requirements specified in § 63.2470(f).

(4) For equipment leaks and pressure relief devices, the requirements specified in §§ 63.2480(e) and (f), 63.2520(d)(4) and (e)(14), and 63.2525(q).

(5) For wastewater streams and liquid streams in open systems within an MCPU, the requirements specified in § 63.2485(i)(2)(iii), (n)(2)(vii), (p), and (q).

(6) For heat exchange systems, the requirements specified in §§ 63.2490(d), 63.2520(e)(16), and 63.2525(r).

(7) The other notification, reports, and records requirements specified in §§ 63.2500(g), 63.2520(e)(5)(ii)(D) and (e)(5)(iii)(M) and (N), and 63.2525(l) and (u).

(h) All affected sources that commenced construction or reconstruction on or before December 17, 2019, must be in compliance with the requirements for pumps in light liquid service in § 63.2480(b)(6) and (c)(10) upon initial startup or on August 12, 2021, whichever is later. All affected sources that commenced construction or reconstruction after December 17, 2019, must be in compliance with the requirements for pumps in light liquid service in § 63.2480(b)(6) and (c)(10) upon initial startup, or on August 12, 2020, whichever is later.

(i) All affected sources that commenced construction or reconstruction on or before December 17, 2019, must be in compliance with the ethylene oxide requirements in §§ 63.2450(h) and (r), 63.2470(b) and (c)(4), 63.2492, 63.2493, 63.2520(d)(5) and (e)(17), and 63.2525(s) and Table 1 to this subpart, item 5, Table 2 to this subpart, item 3, Table 4 to this subpart, item 3, and Table 6 to this subpart, item 3, upon initial startup or on August 12, 2022, whichever is later. All affected sources that commenced construction or reconstruction after December 17, 2019, must be in compliance with the ethylene oxide requirements listed in §§ 63.2450(h) and (r), 63.2470(b) and (c)(4), 63.2492, 63.2493, 63.2520(d)(5) and (e)(17), and 63.2525(s) and Table 1 to this subpart, item 5, Table 2 to this subpart, item 3, Table 4 to this subpart, item 3, and Table 6 to this subpart, item 3, upon initial startup, or on August 12, 2020, whichever is later.

■ 5. Section 63.2450 is amended by:
■ a. Revising paragraphs (a), (c)(2) introductory text, and (e)(1) through (3);
■ b. Adding paragraphs (e)(4) through (7);
■ c. Revising paragraphs (f) introductory text, (g) introductory text, (g)(3)(ii), and (g)(5);
■ d. Adding paragraphs (g)(6) and (7);
■ e. Revising paragraphs (h), (i) introductory text, and (i)(2);
■ f. Adding paragraph (i)(3);
■ g. Revising paragraphs (j) introductory text, (j)(1) introductory text, (j)(1)(i), (j)(2)(iii), and (j)(3) through (5);
■ h. Adding paragraph (j)(6);
■ i. Revising paragraphs (k) introductory text, (k)(1), and (k)(4)(iv);
■ j. Adding paragraphs (k)(7) and (8);
■ k. Revising paragraphs (p) and (r); and
■ l. Adding paragraphs (t), (u), and (v).

The revisions and additions read as follows:

§ 63.2450 What are my general requirements for complying with this subpart?

(a) *General.* You must comply with paragraphs (a)(1) and (2) of this section.

(1) Except as specified in paragraph (a)(2) of this section, you must be in compliance with the emission limits and work practice standards in Tables 1 through 7 to this subpart at all times, except during periods of startup, shutdown, and malfunction (SSM), and you must meet the requirements specified in §§ 63.2455 through 63.2490 (or the alternative means of compliance in § 63.2495, § 63.2500, or § 63.2505), except as specified in paragraphs (b) through (s) of this section. You must meet the notification, reporting, and recordkeeping requirements specified in §§ 63.2515, 63.2520, and 63.2525.

(2) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (a)(1) of this section no longer applies. Instead, you must be in compliance with the emission limits and work practice standards in Tables 1 through 7 to this subpart at all times, and you must meet the requirements specified in §§ 63.2455 through 63.2490 (or the alternative means of compliance in § 63.2495, § 63.2500, or § 63.2505), except as specified in paragraphs (b) through (v) of this section. You must meet the notification, reporting, and recordkeeping requirements specified in §§ 63.2515, 63.2520, and 63.2525.

* * * * *

(c) * * *

(2) Determine the applicable requirements based on the hierarchy presented in paragraphs (c)(2)(i) through (vi) of this section. For a combined stream, the applicable requirements are specified in the highest-listed paragraph in the hierarchy that applies to any of the individual streams that make up the combined stream. For example, if a combined stream consists of emissions from Group 1 batch process vents and any other type of emission stream, then you must comply with the requirements in paragraph (c)(2)(i) of this section for the combined stream; compliance with the requirements in paragraph (c)(2)(i) of this section constitutes compliance for the other emission streams in the combined stream. Two exceptions are that you must comply with the requirements in Table 3 to this subpart and § 63.2465 for all process vents with hydrogen halide and halogen HAP emissions, and recordkeeping requirements for Group 2 applicability or compliance are still required (*e.g.,* the requirement in § 63.2525(e)(3) and (4) to track the number of batches produced and calculate rolling annual emissions for processes with Group 2 batch process vents).

* * * * *

(e) * * *

(1) Except when complying with § 63.2485, if you reduce organic HAP emissions by venting emissions through a closed-vent system to any combination of control devices (except a flare) or recovery devices, you must meet the requirements of paragraph (e)(4) of this section, and the requirements of § 63.982(c) and the requirements referenced therein.

(2) Except as specified in paragraph (e)(5) of this section or except when complying with § 63.2485, if you reduce organic HAP emissions by venting emissions through a closed-vent system to a flare, you must meet the requirements of paragraph (e)(4) of this section, and the requirements of § 63.982(b) and the requirements referenced therein.

(3) Except as specified in paragraphs (e)(3)(i) and (ii) of this section, if you use a halogen reduction device to reduce hydrogen halide and halogen HAP emissions from halogenated vent streams, you must meet the requirements of paragraph (e)(4) of this section, and the requirements of § 63.994 and the requirements referenced therein. If you use a halogen reduction device before a combustion

device, you must determine the halogen atom emission rate prior to the combustion device according to the procedures in § 63.115(d)(2)(v).

(i) Beginning on and after October 13, 2020, performance test reports must be submitted according to the procedures in § 63.2520(f).

(ii) If you use a halogen reduction device other than a scrubber, then you must submit procedures for establishing monitoring parameters to the Administrator as part of your precompliance report as specified in § 63.2520(c)(8).

(4) Beginning no later than the compliance dates specified in § 63.2445(g), the referenced provisions specified in paragraphs (e)(4)(i) through (xvi) of this section do not apply when demonstrating compliance with subpart SS of this part.

(i) The phrase ''Except for equipment needed for safety purposes such as pressure relief devices, low leg drains, high point bleeds, analyzer vents, and open-ended valves or lines'' in § 63.983(a)(3) of subpart SS.

(ii) The second sentence of § 63.983(a)(5) of subpart SS.

(iii) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.984(a) of subpart SS.

(iv) The phrase ''except during periods of start-up, shutdown, and malfunction as specified in the referencing subpart'' in § 63.985(a) of subpart SS.

(v) The phrase ''other than start-ups, shutdowns, or malfunctions'' in § 63.994(c)(1)(ii)(D) of subpart SS.

(vi) Section 63.996(c)(2)(ii) of subpart SS.

(vii) The last sentence of § 63.997(e)(1)(i) of subpart SS.

(viii) Section 63.998(b)(2)(iii) of subpart SS.

(ix) The phrase ''other than start-ups, shutdowns or malfunctions'' in § 63.998(b)(5)(i)(A) of subpart SS.

(x) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(i)(B)(*3*) of subpart SS.

(xi) The phrase ''other than start-ups, shutdowns or malfunctions'' in § 63.998(b)(5)(i)(C) of subpart SS.

(xii) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(ii)(C) of subpart SS.

(xiii) The phrase ''except as provided in paragraphs (b)(6)(i)(A) and (B) of this section'' in § 63.998(b)(6)(i) of subpart SS.

(xiv) The second sentence of § 63.998(b)(6)(ii) of subpart SS.

(xv) Section 63.998(c)(1)(ii)(D), (E), (F), and (G) of subpart SS.

(xvi) Section 63.998(d)(3) of subpart SS.

(5) For any flare that is used to reduce organic HAP emissions from an MCPU, you may elect to comply with the requirements in this paragraph in lieu of the requirements of § 63.982(b) and the requirements referenced therein. However, beginning no later than the compliance dates specified in § 63.2445(g), paragraphs (e)(2) and (f) of this section no longer apply to flares that control ethylene oxide emissions from affected sources in ethylene oxide service as defined in § 63.2550 and flares used to control emissions from MCPUs that produce olefins or polyolefins. Instead, if you reduce organic HAP emissions by venting emissions through a closed-vent system to a steam-assisted, air-assisted, non-assisted, or pressure-assisted multi-point flare that controls ethylene oxide emissions from affected sources in ethylene oxide service as defined in § 63.2550 or is used to control emissions from an MCPU that produces olefins or polyolefins, then you must meet the applicable requirements for flares as specified in §§ 63.670 and 63.671 of subpart CC, including the provisions in Tables 12 and 13 to subpart CC of this part, except as specified in paragraphs (e)(5)(i) through (xiii) of this section. This requirement in this paragraph (e)(5) also applies to any flare using fuel gas from a fuel gas system, of which 50 percent or more of the fuel gas is derived from an MCPU that has processes and/or equipment in ethylene oxide service or that produces olefins or polyolefins, as determined on an annual average basis. For purposes of compliance with this paragraph (e)(5), the following terms are defined in § 63.641 of subpart CC: Assist air, assist steam, center steam, combustion zone, combustion zone gas, flare, flare purge gas, flare supplemental gas, flare sweep gas, flare vent gas, lower steam, net heating value, perimeter assist air, pilot gas, premix assist air, total steam, and upper steam. Also, for purposes of compliance with this paragraph (e)(5), ''MCPUs that produces olefins or polyolefins'' includes only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product. By-products and impurities as defined in § 63.101, as well as wastes and trace contaminants, are not considered products.

(i) When determining compliance with the pilot flame requirements specified in § 63.670(b) and (g), substitute ''pilot flame or flare flame'' for each occurrence of ''pilot flame.''

(ii) When determining compliance with the flare tip velocity and combustion zone operating limits specified in § 63.670(d) and (e), the requirement effectively applies starting with the 15-minute block that includes a full 15 minutes of the flaring event. You are required to demonstrate compliance with the velocity and NHVcz requirements starting with the block that contains the fifteenth minute of a flaring event. You are not required to demonstrate compliance for the previous 15-minute block in which the event started and contained only a fraction of flow.

(iii) Instead of complying with paragraph (o)(2)(i) of § 63.670 of subpart CC, you must develop and implement the flare management plan no later than the compliance dates specified in § 63.2445(g).

(iv) Instead of complying with paragraph (o)(2)(iii) of § 63.670 of subpart CC, if required to develop a flare management plan and submit it to the Administrator, then you must also submit all versions of the plan in portable document format (PDF) to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as confidential business information (CBI). Anything submitted using CEDRI cannot later be claimed to be CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a version with the CBI omitted via CEDRI. A complete plan, including information claimed to be CBI and clearly marked as CBI, must be mailed to the following address: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, CORE CBI Office, U.S. EPA Mailroom (C404–02), Attention: Miscellaneous Organic Chemical Manufacturing Sector Lead, 4930 Old Page Rd., Durham, NC 27703. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c) emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(v) Section 63.670(o)(3)(ii) of subpart CC and all references to § 63.670(o)(3)(ii) of subpart CC do not apply. Instead, the owner or operator

must comply with the maximum flare tip velocity operating limit at all times.

(vi) Substitute ''MCPU'' for each occurrence of ''petroleum refinery.''

(vii) Each occurrence of ''refinery'' does not apply.

(viii) If a pressure-assisted multi-point flare is used as a control device, then you must meet the following conditions:

(A) You are not required to comply with the flare tip velocity requirements in paragraph (d) and (k) of § 63.670 of subpart CC;

(B) You must substitute ''800'' for each occurrence of ''270'' in paragraph (e) of § 63.670 of subpart CC;

(C) You must determine the 15-minute block average NHVvg using only the direct calculation method specified in in paragraph (l)(5)(ii) of § 63.670 of subpart CC;

(D) Instead of complying with paragraph (b) and (g) of § 63.670 of subpart CC, if a pressure-assisted multi-point flare uses cross-lighting on a stage of burners rather than having an individual pilot flame on each burner, then you must operate each stage of the pressure-assisted multi-point flare with a flame present at all times when regulated material is routed to that stage of burners. Each stage of burners that cross-lights in the pressure-assisted multi-point flare must have at least two pilots with at least one continuously lit and capable of igniting all regulated material that is routed to that stage of burners. Each 15-minute block during which there is at least one minute where no pilot flame is present on a stage of burners when regulated material is routed to the flare is a deviation of the standard. Deviations in different 15-minute blocks from the same event are considered separate deviations. The pilot flame(s) on each stage of burners that use cross-lighting must be continuously monitored by a thermocouple or any other equivalent device used to detect the presence of a flame;

(E) Unless you choose to conduct a cross-light performance demonstration as specified in this paragraph (e)(5)(viii)(E), you must ensure that if a stage of burners on the flare uses cross-lighting, that the distance between any two burners in series on that stage is no more than 6 feet when measured from the center of one burner to the next burner. A distance greater than 6 feet between any two burners in series may be used provided you conduct a performance demonstration that confirms the pressure-assisted multi-point flare will cross-light a minimum of three burners and the spacing between the burners and location of the pilot flame must be representative of the projected installation. The compliance demonstration must be approved by the permitting authority and a copy of this approval must be maintained onsite. The compliance demonstration report must include: A protocol describing the test methodology used, associated test method QA/QC parameters, the waste gas composition and NHVcz of the gas tested, the velocity of the waste gas tested, the pressure-assisted multi-point flare burner tip pressure, the time, length, and duration of the test, records of whether a successful cross-light was observed over all of the burners and the length of time it took for the burners to cross-light, records of maintaining a stable flame after a successful cross-light and the duration for which this was observed, records of any smoking events during the cross-light, waste gas temperature, meteorological conditions (*e.g.,* ambient temperature, barometric pressure, wind speed and direction, and relative humidity), and whether there were any observed flare flameouts; and

(F) You must install and operate pressure monitor(s) on the main flare header, as well as a valve position indicator monitoring system for each staging valve to ensure that the flare operates within the proper range of conditions as specified by the manufacturer. The pressure monitor must meet the requirements in Table 13 to subpart CC of this part.

(G) If a pressure-assisted multi-point flare is operating under the requirements of an approved alternative means of emission limitations, you must either continue to comply with the terms of the alternative means of emission limitations or comply with the provisions in paragraphs (e)(5)(viii)(A) through (F) of this section.

(ix) If you choose to determine compositional analysis for net heating value with a continuous process mass spectrometer, then you must comply with the requirements specified in paragraphs (e)(5)(ix)(A) through (G) of this section.

(A) You must meet the requirements in § 63.671(e)(2). You may augment the minimum list of calibration gas components found in § 63.671(e)(2) with compounds found during a pre-survey or known to be in the gas through process knowledge.

(B) Calibration gas cylinders must be certified to an accuracy of 2 percent and traceable to National Institute of Standards and Technology (NIST) standards.

(C) For unknown gas components that have similar analytical mass fragments to calibration compounds, you may report the unknowns as an increase in the overlapped calibration gas compound. For unknown compounds that produce mass fragments that do not overlap calibration compounds, you may use the response factor for the nearest molecular weight hydrocarbon in the calibration mix to quantify the unknown component's NHVvg.

(D) You may use the response factor for n-pentane to quantify any unknown components detected with a higher molecular weight than n-pentane.

(E) You must perform an initial calibration to identify mass fragment overlap and response factors for the target compounds.

(F) You must meet applicable requirements in Performance Specification 9 of 40 CFR part 60, appendix B, for continuous monitoring system acceptance including, but not limited to, performing an initial multi-point calibration check at three concentrations following the procedure in Section 10.1 and performing the periodic calibration requirements listed for gas chromatographs in Table 13 to subpart CC of this part, for the process mass spectrometer. You may use the alternative sampling line temperature allowed under Net Heating Value by Gas Chromatograph in Table 13 to subpart CC of this part.

(G) The average instrument calibration error (CE) for each calibration compound at any calibration concentration must not differ by more than 10 percent from the certified cylinder gas value. The CE for each component in the calibration blend must be calculated using Equation 1 to this paragraph (e)(5)(ix)(G).

$$CE = \frac{C_m - C_a}{C_a} x\ 100 \text{ (Eq. 1)}$$

Where:

Cm = Average instrument response (ppm).

Ca = Certified cylinder gas value (ppm).

(x) If you use a gas chromatograph or mass spectrometer for compositional analysis for net heating value, then you may choose to use the CE of $NHV_{measured}$ versus the cylinder tag value NHV as the measure of agreement for daily calibration and quarterly audits in lieu of determining the compound-specific CE. The CE for NHV at any calibration level must not differ by more than 10 percent from the certified cylinder gas value. The CE for must be calculated using Equation 2 to this paragraph (e)(5)(x).

$$CE = \frac{NHV_{measured} - NHV_a}{NHV_a} x\ 100 \text{ (Eq. 2)}$$

Where:

$NHV_{measured}$ = Average instrument response (Btu/scf).

NHV_a = Certified cylinder gas value (Btu/scf).

(xi) Instead of complying with paragraph (q) of § 63.670 of subpart CC, you must comply with the reporting requirements specified in § 63.2520(d)(3) and (e)(11).

(xii) Instead of complying with paragraph (p) of § 63.670 of subpart CC, you must keep the flare monitoring records specified in § 63.2525(m).

(xiii) You may elect to comply with the alternative means of emissions limitation requirements specified in paragraph (r) of § 63.670 of subpart CC in lieu of the requirements in paragraphs (d) through (f) of § 63.670 of subpart CC, as applicable. However, instead of complying with paragraph (r)(3)(iii) of § 63.670 of subpart CC, you must also submit the alternative means of emissions limitation request to the following address: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, U.S. EPA Mailroom (C404–02), Attention: Miscellaneous Organic Chemical Manufacturing Sector Lead, 4930 Old Page Rd., Durham, NC 27703.

(6) Beginning no later than the compliance dates specified in § 63.2445(g), the use of a bypass line at any time on a closed vent system to divert emissions subject to the requirements in Tables 1 through 7 to this subpart to the atmosphere or to a control device not meeting the requirements specified in Tables 1 through 7 to this subpart is an emissions standards deviation. You must also comply with the requirements specified in paragraphs (e)(6)(i) through (v) of this section, as applicable:

(i) If you are subject to the bypass monitoring requirements of § 63.148(f) of subpart G, then you must continue to comply with the requirements in § 63.148(f) of subpart G and the recordkeeping and reporting requirements in §§ 63.148(j)(2) and (3) of subpart G, and (h)(3) of subpart G, in addition to the applicable requirements specified in § 63.2485(q), the recordkeeping requirements specified in § 63.2525(n), and the reporting requirements specified in § 63.2520(e)(12).

(ii) If you are subject to the bypass monitoring requirements of § 63.172(j) of subpart H, then you must continue to comply with the requirements in § 63.172(j) of subpart H and the recordkeeping and reporting requirements in § 63.118(a)(3) and (4), and (f)(3) and (4) of subpart G, in addition to the applicable requirements specified in §§ 63.2480(f) and 63.2485(q), the recordkeeping requirements specified in § 63.2525(n), and the reporting requirements specified in § 63.2520(e)(12).

(iii) If you are subject to the bypass monitoring requirements of § 63.983(a)(3) of subpart SS, then you must continue to comply with the requirements in § 63.983(a)(3) of subpart SS and the recordkeeping and reporting requirements in §§ 63.998(d)(1)(ii) and 63.999(c)(2) of subpart SS, in addition to the requirements specified in § 63.2450(e)(4), the recordkeeping requirements specified in § 63.2525(n), and the reporting requirements specified in § 63.2520(e)(12).

(iv) If you are subject to the bypass monitoring requirements of § 65.143(a)(3) of this chapter, then you must continue to comply with the requirements in § 65.143(a)(3) and the recordkeeping and reporting requirements in §§ 65.163(a)(1) and 65.166(b) of this chapter; in addition to the applicable requirements specified in § 63.2480(f), the recordkeeping requirements specified in § 63.2525(n), and the reporting requirements specified in § 63.2520(e)(12).

(v) For purposes of compliance with this paragraph (e)(6), §§ 63.148(f)(3) of subpart G, and 63.172(j)(3) of subpart H, the phrase ''Except for equipment needed for safety purposes such as pressure relief devices, low leg drains, high point bleeds, analyzer vents, and open-ended valves or lines'' in § 63.983(a)(3) of subpart SS, and the phrase ''Except for pressure relief devices needed for safety purposes, low leg drains, high point bleeds, analyzer vents, and open-ended valves or lines'' in § 65.143(a)(3) of this chapter do not apply; instead, the exemptions specified in paragraphs (e)(6)(v)(A) and (B) of this section apply.

(A) Except for pressure relief devices subject to § 63.2480(e)(4), equipment such as low leg drains and equipment subject to the requirements specified in § 63.2480 are not subject to this paragraph (e)(6).

(B) Open-ended valves or lines that use a cap, blind flange, plug, or second valve and follow the requirements specified in 40 CFR 60.482–6(a)(2), (b), and (c) or follow requirements codified in another regulation that are the same as 40 CFR 60.482–6(a)(2), (b), and (c) are not subject to this paragraph (e)(6).

(7) Beginning no later than the compliance dates specified in § 63.2445(g), if you reduce organic HAP emissions by venting emissions through a closed-vent system to an adsorber(s) that cannot be regenerated or a regenerative adsorber(s) that is regenerated offsite, then you must comply with paragraphs (e)(4) and (6) of this section and the requirements in § 63.983, and you must install a system of two or more adsorber units in series and comply with the requirements specified in paragraphs (e)(7)(i) through (iii) of this section.

(i) Conduct an initial performance test or design evaluation of the adsorber and establish the breakthrough limit and adsorber bed life.

(ii) Monitor the HAP or total organic compound (TOC) concentration through a sample port at the outlet of the first adsorber bed in series according to the schedule in paragraph (e)(7)(iii)(B) of this section. You must measure the concentration of HAP or TOC using either a portable analyzer, in accordance with Method 21 of 40 CFR part 60, appendix A–7, using methane, propane, isobutylene, or the primary HAP being controlled as the calibration gas or Method 25A of 40 CFR part 60, appendix A–7, using methane, propane, or the primary HAP being controlled as the calibration gas.

(iii) Comply with paragraph (e)(7)(iii)(A) of this section, and comply with the monitoring frequency according to paragraph (e)(7)(iii)(B) of this section.

(A) The first adsorber in series must be replaced immediately when breakthrough, as defined in § 63.2550(i), is detected between the first and second adsorber. The original second adsorber (or a fresh canister) will become the new first adsorber and a fresh adsorber will become the second adsorber. For purposes of this paragraph (e)(7)(iii)(A), ''immediately'' means within 8 hours of the detection of a breakthrough for adsorbers of 55 gallons or less, and within 24 hours of the detection of a breakthrough for adsorbers greater than 55 gallons. You must monitor at the outlet of the first adsorber within 3 days of replacement to confirm it is performing properly.

(B) Based on the adsorber bed life established according to paragraph (e)(7)(i) of this section and the date the adsorbent was last replaced, conduct monitoring to detect breakthrough at least monthly if the adsorbent has more than 2 months of life remaining, at least weekly if the adsorbent has between 2 months and 2 weeks of life remaining, and at least daily if the adsorbent has 2 weeks or less of life remaining.

(f) *Requirements for flare compliance assessments.* Except as specified in paragraph (e)(5) of this section, you must comply with paragraphs (f)(1) and (2) of this section.

* * * * *

(g) *Requirements for performance tests.* The requirements specified in paragraphs (g)(1) through (7) of this

section apply instead of or in addition to the requirements specified in subpart SS of this part.

* * * * *

(3) * * *

(ii) If you elect to comply with the outlet TOC concentration emission limits in Tables 1 through 7 to this subpart, and the uncontrolled or inlet gas stream to the control device contains greater than 10 percent (volume concentration) carbon disulfide, you must use Method 18 or Method 15 of 40 CFR part 60, appendix A, to separately determine the carbon disulfide concentration. Calculate the total HAP or TOC emissions by totaling the carbon disulfide emissions measured using Method 18 or 15 of 40 CFR part 60, appendix A, and the other HAP emissions measured using Method 18 or 25A of 40 CFR part 60, appendix A.

* * * * *

(5) Section 63.997(c)(1) does not apply. For the purposes of this subpart, results of all initial compliance demonstrations must be included in the notification of compliance status report, which is due 150 days after the compliance date, as specified in § 63.2520(d)(1). If the initial compliance demonstration includes a performance test and the results are submitted electronically via CEDRI in accordance with § 63.2520(f), the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted may be submitted in the notification of compliance status report in lieu of the performance test results. The performance test results must be submitted to CEDRI by the date the notification of compliance status report is submitted.

(6) Beginning no later than the compliance dates specified in § 63.2445(g), in lieu of the requirements specified in § 63.7(e)(1) of subpart A you must conduct performance tests under such conditions as the Administrator specifies based on representative performance of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown. You may not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you must make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(7) Comply with the requirements in § 63.2450(e)(4), as applicable.

(h) *Design evaluation.* To determine the percent reduction of a small control device that is used to comply with an emission limit specified in Table 1, 2, 3, or 5 to this subpart, you may elect to conduct a design evaluation as specified in § 63.1257(a)(1) instead of a performance test as specified in subpart SS of this part. You must establish the value(s) and basis for the operating limits as part of the design evaluation. For continuous process vents, the design evaluation must be conducted at maximum representative operating conditions for the process, unless the Administrator specifies or approves alternate operating conditions. For transfer racks, the design evaluation must demonstrate that the control device achieves the required control efficiency during the reasonably expected maximum transfer loading rate. Beginning no later than the compliance dates specified in § 63.2445(i), this paragraph (h) does not apply to process vents in ethylene oxide service as defined in § 63.2550.

(i) *Outlet concentration correction for combustion devices.* Except as specified in paragraph (i)(3) of this section, when § 63.997(e)(2)(iii)(C) requires you to correct the measured concentration at the outlet of a combustion device to 3-percent oxygen if you add supplemental combustion air, the requirements in either paragraph (i)(1) or (2) of this section apply for the purposes of this subpart.

* * * * *

(2) You must correct the measured concentration for supplemental gases using Equation 1 in § 63.2460(c)(6); you may use process knowledge and representative operating data to determine the fraction of the total flow due to supplemental gas.

(3) Beginning no later than the compliance dates specified in § 63.2445(g), paragraphs (i)(1) and (2) of this section no longer apply. Instead, when § 63.997(e)(2)(iii)(C) requires you to correct the measured concentration at the outlet of a combustion device to 3-percent oxygen if you add supplemental combustion air, you must follow the procedures in § 63.997(e)(2)(iii)(C) to perform the concentration correction, except you may also use Method 3A of 40 CFR part 60, appendix A–2, to determine the oxygen concentration.

(j) *Continuous emissions monitoring systems.* Each continuous emissions monitoring system (CEMS) must be installed, operated, and maintained according to the requirements in § 63.8 of subpart A and paragraphs (j)(1) through (6) of this section.

(1) Each CEMS must be installed, operated, and maintained according to the applicable Performance Specification of 40 CFR part 60, appendix B, and the applicable Quality Assurance Procedures of 40 CFR part 60, appendix F, and according to paragraph (j)(2) of this section, except as specified in paragraph (j)(1)(i) of this section. For any CEMS meeting Performance Specification 8 of 40 CFR part 60, appendix B, you must also comply with procedure 1 of 40 CFR part 60, appendix F. Locate the sampling probe or other interface at a measurement location such that you obtain representative measurements of emissions from the regulated source. For CEMS installed after August 12, 2020, conduct a performance evaluation of each CEMS within 180 days of installation of the monitoring system.

(i) If you wish to use a CEMS other than a Fourier Transform Infrared Spectroscopy (FTIR) meeting the requirements of Performance Specification 15 of 40 CFR part 60, appendix B, to measure hydrogen halide, other than hydrogen chloride, and halogen HAP or CEMS meeting the requirements of Performance Specification 18 of 40 CFR part 60, appendix B, to measure hydrogen chloride before we promulgate a Performance Specification for such CEMS, you must prepare a monitoring plan and submit it for approval in accordance with the procedures specified in § 63.8 of subpart A.

* * * * *

(2) * * *

(iii) For CEMS meeting Performance Specification 8 of 40 CFR part 60, appendix B, used to monitor performance of a noncombustion device, determine the predominant organic HAP using either process knowledge or the screening procedures of Method 18 of 40 CFR part 60, appendix A–6, on the control device inlet stream, calibrate the monitor on the predominant organic HAP, and report the results as C_I. Use Method 18 of 40 CFR part 60, appendix A–6, Method 320 of appendix A to this part, ASTM D6420–18 (incorporated by reference, see § 63.14), or any approved alternative as the reference method for the relative accuracy tests, and report the results as C_I.

(3) You must conduct a performance evaluation of each CEMS according to the requirements in § 63.8 of subpart A and according to the applicable Performance Specification of 40 CFR part 60, appendix B, except that the schedule in § 63.8(e)(4) of subpart A does not apply, and before October 13, 2020, the results of the performance evaluation must be included in the

notification of compliance status report. Unless otherwise specified in this subpart, beginning on and after October 13, 2020, the results of the performance evaluation must be submitted in accordance with § 63.2520(g).

(4) The CEMS data must be reduced to operating day or operating block averages computed using valid data consistent with the data availability requirements specified in § 63.999(c)(6)(i)(B) through (D), except monitoring data also are sufficient to constitute a valid hour of data if measured values are available for at least two of the 15-minute periods during an hour when calibration, quality assurance, or maintenance activities are being performed. An operating block is a period of time from the beginning to end of batch operations within a process. Operating block averages may be used only for batch process vent data. In computing operating day or operating block averages to determine compliance with this subpart, you must exclude monitoring data recorded during CEMS breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, or other quality assurance activities. Out-of-control periods are as specified in § 63.8(c)(7) of subpart A.

(5) If you add supplemental gases, you must comply with paragraphs (j)(5)(i) and (ii) of this section.

(i) Except as specified in paragraph (j)(5)(ii) of this section, correct the measured concentrations in accordance with paragraph (i) of this section and § 63.2460(c)(6).

(ii) Beginning no later than the compliance dates specified in § 63.2445(g), you must use Performance Specification 3 of 40 CFR part 60, appendix B, to certify your oxygen CEMS, and you must comply with procedure 1 of 40 CFR part 60, appendix F. Use Method 3A of 40 CFR part 60, appendix A–2, as the reference method when conducting a relative accuracy test audit.

(6) Beginning no later than the compliance dates specified in § 63.2445(g), in lieu of the requirements specified in § 63.8(d)(3) of subpart A you must keep the written procedures required by § 63.8(d)(2) of subpart A on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2) of subpart A. In addition to the information required in § 63.8(d)(2) of subpart A, your written procedures for CEMS must include the information in paragraphs (j)(6)(i) through (vi) of this section:

(i) Description of CEMS installation location.

(ii) Description of the monitoring equipment, including the manufacturer and model number for all monitoring equipment components and the span of the analyzer.

(iii) Routine quality control and assurance procedures.

(iv) Conditions that would trigger a CEMS performance evaluation, which must include, at a minimum, a newly installed CEMS; a process change that is expected to affect the performance of the CEMS; and the Administrator's request for a performance evaluation under section 114 of the Clean Air Act.

(v) Ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1) and (3), (c)(4)(ii), and (c)(7) and (8) of subpart A;

(vi) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c) and (e)(1) of subpart A.

(k) *Continuous parameter monitoring.* The provisions in paragraphs (k)(1) through (8) of this section apply in addition to the requirements for continuous parameter monitoring system (CPMS) in subpart SS of this part.

(1) You must comply with paragraphs (k)(1)(i) and (ii) of this section.

(i) Except as specified in paragraph (k)(1)(ii) of this section, record the results of each calibration check and all maintenance performed on the CPMS as specified in § 63.998(c)(1)(ii)(A).

(ii) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (k)(1)(i) of this section no longer applies. Instead, you must record the results of each calibration check and all maintenance performed on the CPMS as specified in § 63.998(c)(1)(ii)(A), except you must record all maintenance, not just preventative maintenance.

* * * * *

(4) * * *

(iv) Recording the downstream temperature and temperature difference across the catalyst bed as specified in § 63.998(a)(2)(ii)(B)(*2*) and (c)(2)(ii) is not required.

* * * * *

(7) Beginning no later than the compliance dates specified in § 63.2445(g), the manufacturer's specifications or your written procedures must include a schedule for calibrations, preventative maintenance procedures, a schedule for preventative maintenance, and corrective actions to be taken if a calibration fails. If a CPMS calibration fails, the CPMS is considered to be inoperative until you take corrective action and the system passes calibration. You must record the nature and cause of instances when the CPMS is inoperative and the corrective action taken.

(8) You must comply with the requirements in paragraph (e)(4) of this section, as applicable.

* * * * *

(p) *Original safety device requirements.* Except as specified in paragraph (t) of this section, opening a safety device, as defined in § 63.2550, is allowed at any time conditions require it to avoid unsafe conditions.

* * * * *

(r) *Surge control vessels and bottoms receivers.* For each surge control vessel or bottoms receiver that meets the capacity and vapor pressure thresholds for a Group 1 storage tank, you must meet emission limits and work practice standards specified in Table 4 to this subpart. Beginning no later than the compliance dates specified in § 63.2445(i), for each surge control vessel and bottoms receiver in ethylene oxide service as defined in § 63.2550, you must also meet the applicable process vent requirements specified in §§ 63.2492 and 63.2493(a) through (c).

* * * * *

(t) *New safety device requirements.* Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (p) of this section no longer applies. Instead, you must comply with the requirements specified in § 63.2480(e).

(u) *General duty.* Beginning no later than the compliance dates specified in § 63.2445(g), at all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on

information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(v) *Maintenance vents.* Beginning no later than the compliance dates specified in § 63.2445(g), you may designate a process vent as a maintenance vent if the vent is only used as a result of startup, shutdown, maintenance, or inspection of equipment where equipment is emptied, depressurized, degassed, or placed into service. You must comply with the applicable requirements in paragraphs (v)(1) through (3) of this section for each maintenance vent. Any vent designated as a maintenance vent is only subject to the maintenance vent provisions in this paragraph (v) and the associated recordkeeping and reporting requirements in §§ 63.2525(p) and 63.2520(e)(14), respectively. You do not need to designate a maintenance vent as a Group 1 or Group 2 process vent nor identify maintenance vents in a Notification of Compliance Status report.

(1) Prior to venting to the atmosphere, remove process liquids from the equipment as much as practical and depressurize the equipment to either: A flare meeting the requirements of paragraph (e)(2) or (5) of this section, as applicable, or a non-flare control device meeting the requirements in paragraph (e)(4) of this section and the requirements specified in § 63.982(c)(2) of subpart SS until one of the following conditions, as applicable, is met.

(i) The vapor in the equipment served by the maintenance vent has a lower explosive limit (LEL) of less than 10 percent and has an outlet concentration less than or equal to 20 ppmv hydrogen halide and halogen HAP.

(ii) If there is no ability to measure the LEL of the vapor in the equipment based on the design of the equipment, the pressure in the equipment served by the maintenance vent is reduced to 5 pounds per square inch gauge (psig) or less. Upon opening the maintenance vent, active purging of the equipment cannot be used until the LEL of the vapors in the maintenance vent (or inside the equipment if the maintenance is a hatch or similar type of opening) is less than 10 percent.

(iii) The equipment served by the maintenance vent contains less than 50 pounds of total volatile organic compounds (VOC).

(iv) If, after applying best practices to isolate and purge equipment served by a maintenance vent, none of the applicable criterion in paragraphs (v)(1)(i) through (iii) of this section can be met prior to installing or removing a blind flange or similar equipment blind, then the pressure in the equipment served by the maintenance vent must be reduced to 2 psig or less before installing or removing the equipment blind. During installation or removal of the equipment blind, active purging of the equipment may be used provided the equipment pressure at the location where purge gas is introduced remains at 2 psig or less.

(2) Except for maintenance vents complying with the alternative in paragraph (v)(1)(iii) of this section, you must determine the LEL or, if applicable, equipment pressure using process instrumentation or portable measurement devices and follow procedures for calibration and maintenance according to manufacturer's specifications.

(3) For maintenance vents complying with the alternative in paragraph (v)(1)(iii) of this section, you must determine mass of VOC in the equipment served by the maintenance vent based on the equipment size and contents after considering any contents drained or purged from the equipment. Equipment size may be determined from equipment design specifications. Equipment contents may be determined using process knowledge.

■ 6. Section 63.2455 is amended by revising paragraph (a) to read as follows:

§ 63.2455 What requirements must I meet for continuous process vents?

(a) You must meet each emission limit in Table 1 to this subpart that applies to your continuous process vents, and you must meet each applicable requirement specified in paragraphs (b) through (c) of this section and §§ 63.2492 and 63.2493(a) through (c).

* * * * *

■ 7. Section 63.2460 is amended by revising paragraphs (a), (b)(5) introductory text, (b)(5)(iii), (b)(6) introductory text, (c)(2)(i), (ii), and (v), the first sentence of (c)(6) introductory text, (c)(9) introductory text, (c)(9)(ii) introductory text, (c)(9)(ii)(D), and (c)(9)(iii) and (iv) to read as follows:

§ 63.2460 What requirements must I meet for batch process vents?

(a) *General.* You must meet each emission limit in Table 2 to this subpart that applies to you, and you must meet each applicable requirement specified in paragraphs (b) and (c) of this section and §§ 63.2492 and 63.2493(a) through (c).

(b) * * *

(5) You may elect to designate the batch process vents within a process as Group 1 and not calculate uncontrolled emissions if you comply with one of the situations in paragraph (b)(5)(i), (ii), or (iii) of this section.

* * * * *

(iii) If you comply with an emission limit using a flare that meets the requirements specified in § 63.987 or § 63.2450(e)(5), as applicable.

(6) You may change from Group 2 to Group 1 in accordance with either paragraph (b)(6)(i) or (ii) of this section. Before October 13, 2020, you must comply with the requirements of this section and submit the test report. Beginning on and after October 13, 2020, you must comply with the requirements of this section and submit the performance test report for the demonstration required in § 63.1257(b)(8) in accordance with § 63.2520(f).

* * * * *

(c) * * *

(2) * * *

(i) To demonstrate initial compliance with a percent reduction emission limit in Table 2 to this subpart, you must compare the sums of the controlled and uncontrolled emissions for the applicable Group 1 batch process vents within the process, and show that the specified reduction is met. This requirement does not apply if you comply with the emission limits of Table 2 to this subpart by using a flare that meets the requirements of § 63.987 or 63.2450(e)(5), as applicable.

(ii) When you conduct a performance test or design evaluation for a non-flare control device used to control emissions from batch process vents, you must establish emission profiles and conduct the test under worst-case conditions according to § 63.1257(b)(8) instead of under normal operating conditions as specified in § 63.7(e)(1) of subpart A or the conditions as specified in § 63.2450(g)(6). The requirements in § 63.997(e)(1)(i) and (iii) also do not apply for performance tests conducted to determine compliance with the emission limits for batch process vents. For purposes of this subpart, references in § 63.997(b)(1) to ''methods specified in § 63.997(e)'' include the methods specified in § 63.1257(b)(8).

* * * * *

(v) If a process condenser is used for boiling operations in which HAP (not as an impurity) is heated to the boiling point, you must demonstrate that it is properly operated according to the procedures specified in § 63.1257(d)(2)(i)(C)(*4*)(*ii*) and (d)(3)(iii)(B), and the demonstration

must occur only during the boiling operation. The reference in § 63.1257(d)(3)(iii)(B) to the alternative standard in § 63.1254(c) means § 63.2505 for the purposes of this subpart. As an alternative to measuring the exhaust gas temperature, as required by § 63.1257(d)(3)(iii)(B), you may elect to measure the liquid temperature in the receiver.

* * * * *

(6) *Outlet concentration correction for supplemental gases.* If you use a control device other than a combustion device to comply with a TOC, organic HAP, or hydrogen halide and halogen HAP outlet concentration emission limit for batch process vents, you must correct the actual concentration for supplemental gases using Equation 1 to this paragraph (e)(6); you may use process knowledge and representative operating data to determine the fraction of the total flow due to supplemental gas.

* * * * *

(9) *Requirements for a biofilter.* If you use a biofilter to meet either the 95-percent reduction requirement or outlet concentration requirement specified in Table 2 to this subpart, you must meet the requirements specified in paragraphs (c)(9)(i) through (vi) of this section.

* * * * *

(ii) *Performance tests.* To demonstrate initial compliance, you must conduct a performance test according to the procedures in §§ 63.2450(g) and 63.997 of subpart SS, and paragraphs (c)(9)(ii)(A) through (D) of this section. The design evaluation option for small control devices is not applicable if you use a biofilter.

* * * * *

(D) Before October 13, 2020, submit a performance test report as specified in § 63.999(a)(2)(i) and (ii) and include the records from paragraph (c)(9)(ii)(B) of this section. Beginning on and after October 13, 2020, you must submit a performance test report as specified in § 63.2520(f).

(iii) *Monitoring requirements.* Use either a biofilter bed temperature monitoring device (or multiple devices) capable of providing a continuous record or an organic monitoring device capable of providing a continuous record. Comply with the requirements in § 63.2450(e)(4), the general requirements for monitoring in § 63.996, and keep records of temperature or other parameter monitoring results as specified in § 63.998(b) and (c), as applicable. If you monitor temperature, the operating temperature range must be based on only the temperatures measured during the performance test; these data may not be supplemented by engineering assessments or manufacturer's recommendations as otherwise allowed in § 63.999(b)(3)(ii)(A). If you establish the operating range (minimum and maximum temperatures) using data from previous performance tests in accordance with § 63.996(c)(6), replacement of the biofilter media with the same type of media is not considered a process change under § 63.997(b)(1). You may expand your biofilter bed temperature operating range by conducting a repeat performance test that demonstrates compliance with the 95-percent reduction requirement or outlet concentration limit, as applicable.

(iv) *Repeat performance tests.* You must conduct a repeat performance test using the applicable methods specified in §§ 63.2450(g) and 63.997 within 2 years following the previous performance test and within 150 days after each replacement of any portion of the biofilter bed media with a different type of media or each replacement of more than 50 percent (by volume) of the biofilter bed media with the same type of media.

■ 8. Section 63.2465 is amended by revising paragraphs (c) introductory text and (d)(2) to read as follows:

§ 63.2465 What requirements must I meet for process vents that emit hydrogen halide and halogen HAP or HAP metals?

* * * * *

(c) If collective uncontrolled hydrogen halide and halogen HAP emissions from the process vents within a process are greater than or equal to 1,000 pounds per year (lb/yr), you must comply with the requirements in § 63.2450(e)(4) and the requirements of § 63.994 and the requirements referenced therein, except as specified in paragraphs (c)(1) through (3) of this section.

* * * * *

(d) * * *

(2) Conduct an initial performance test of each control device that is used to comply with the emission limit for HAP metals specified in Table 3 to this subpart. Conduct the performance test according to the procedures in §§ 63.2450(g) and 63.997. Use Method 29 of 40 CFR part 60, appendix A, to determine the HAP metals at the inlet and outlet of each control device, or use Method 5 of 40 CFR part 60, appendix A, to determine the total particulate matter (PM) at the inlet and outlet of each control device. You may use ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 63.14) as an alternative to Method 29 (portion for mercury only) as a method for measuring mercury concentrations of 0.5 to 100 micrograms per standard cubic meter. You have demonstrated initial compliance if the overall reduction of either HAP metals or total PM from the process is greater than or equal to 97 percent by weight.

* * * * *

■ 9. Section 63.2470 is amended by revising paragraph (a), adding paragraph (b), revising paragraphs (c) and (e)(3), and adding paragraph (f) to read as follows:

§ 63.2470 What requirements must I meet for storage tanks?

(a) *General.* You must meet each emission limit in Table 4 to this subpart that applies to your storage tanks, and except as specified in paragraph (b) of this section, you must also meet each applicable requirement specified in paragraphs (c) through (f) of this section and §§ 63.2492 and 63.2493(a) through (c).

(b) *General for storage tanks in ethylene oxide service.* On and after the compliance dates specified in § 63.2445(i), paragraphs (d) and (e) of this section do not apply to storage tanks in ethylene oxide service as defined in § 63.2550.

(c) *Exceptions to subparts SS and WW of this part.* (1) Except as specified in paragraph (c)(4)(ii) of this section, if you conduct a performance test or design evaluation for a control device used to control emissions only from storage tanks, you must establish operating limits, conduct monitoring, and keep records using the same procedures as required in subpart SS of this part for control devices used to reduce emissions from process vents instead of the procedures specified in §§ 63.985(c), 63.998(d)(2)(i), and 63.999(b)(2). You must also comply with the requirements in § 63.2450(e)(4), as applicable.

(2) Except as specified in paragraph (c)(4) of this section, when the term ''storage vessel'' is used in subparts SS and WW of this part, the term ''storage tank,'' as defined in § 63.2550 applies for the purposes of this subpart.

(3) For adsorbers that cannot be regenerated or regenerative adsorbers that are regenerated offsite, you must comply with the monitoring requirements in § 63.2450(e)(7) in lieu of § 63.995(c).

(4) Beginning no later than the compliance dates specified in § 63.2445(i), you must comply with paragraphs (c)(4)(i) and (ii) of this section.

(i) The exemptions for ''vessels storing organic liquids that contain HAP only as impurities'' and ''pressure

vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere'' listed in the definition of ''storage tank'' in § 63.2550 do not apply for storage tanks in ethylene oxide service.

(ii) For storage tanks in ethylene oxide service as defined in § 63.2550, you may not use a design evaluation to determine the percent reduction of any control device that is used to comply with an emission limit specified in Table 4 to this subpart.

* * * * *

(e) * * *

(3) You may elect to set a pressure relief device to a value less than the 2.5 psig required in § 63.1253(f)(5) if you provide rationale in your notification of compliance status report explaining why the alternative value is sufficient to prevent breathing losses at all times.

* * * * *

(f) *Storage tank degassing.* Beginning no later than the compliance dates specified in § 63.2445(g), for each storage tank subject to item 1 of Table 4 to this subpart, you must comply with paragraphs (f)(1) through (3) of this section during storage tank shutdown operations (*i.e.,* emptying and degassing of a storage tank) until the vapor space concentration in the storage tank is less than 10 percent of the LEL. You must determine the LEL using process instrumentation or portable measurement devices and follow procedures for calibration and maintenance according to manufacturer's specifications.

(1) Remove liquids from the storage tank as much as practicable.

(2) Comply with one of the following:

(i) Reduce emissions of total organic HAP by venting emissions through a closed vent system to a flare.

(ii) Reduce emissions of total organic HAP by 95 weight-percent by venting emissions through a closed vent system to any combination of non-flare control devices.

(iii) Reduce emissions of total organic HAP by routing emissions to a fuel gas system or process and meet the requirements specified in § 63.982(d) and the applicable requirements in § 63.2450(e)(4).

(3) Maintain records necessary to demonstrate compliance with the requirements in § 63.2450(u) including, if appropriate, records of existing standard site procedures used to empty and degas (deinventory) equipment for safety purposes.

■ 10. Section 63.2475 is amended by revising paragraph (a) to read as follows:

§ 63.2475 What requirements must I meet for transfer racks?

(a) You must comply with each emission limit and work practice standard in Table 5 to this subpart that applies to your transfer racks, and you must meet each applicable requirement in paragraph (b) of this section.

* * * * *

■ 11. Section 63.2480 is amended by:

■ a. Revising paragraphs (a), (b) introductory text, and (b)(1), (2), and (5);

■ b. Adding paragraphs (b)(6) and (7);

■ c. Revising paragraphs (c) introductory text and (c)(5); and

■ d. Adding paragraphs (c)(10) and (11), (e), and (f).

The revisions and additions read as follows:

§ 63.2480 What requirements must I meet for equipment leaks?

(a) You must meet each requirement in Table 6 to this subpart that applies to your equipment leaks, except as specified in paragraphs (b) through (f) of this section. For each light liquid pump, valve, and connector in ethylene oxide service as defined in § 63.2550(i), you must also meet the applicable requirements specified in §§ 63.2492 and 63.2493(d) and (e).

(b) Except as specified in paragraphs (b)(6) and (7) of this section, if you comply with either subpart H or UU of this part, you may elect to comply with the provisions in paragraphs (b)(1) through (5) of this section as an alternative to the referenced provisions in subpart H or UU of this part.

(1) The requirements for pressure testing in § 63.178(b) or § 63.1036(b) may be applied to all processes, not just batch processes.

(2) For the purposes of this subpart, pressure testing for leaks in accordance with § 63.178(b) or § 63.1036(b) is not required after reconfiguration of an equipment train if flexible hose connections are the only disturbed equipment.

* * * * *

(5) Except as specified in paragraph (b)(6) of this section, for pumps in light liquid service in an MCPU that has no continuous process vents and is part of an existing source, you may elect to consider the leak definition that defines a leak to be 10,000 parts per million (ppm) or greater as an alternative to the values specified in § 63.1026(b)(2)(i) through (iii) or § 63.163(b)(2).

(6) Beginning no later than the compliance dates specified in § 63.2445(h), paragraph (b)(5) of this section no longer applies.

(7) For each piece of equipment that is subject to Table 6 to this subpart and is also subject to periodic monitoring with EPA Method 21 of 40 CFR part 60, appendix A–7, and is added to an affected source after December 17, 2019, or replaces equipment at an affected source after December 17, 2019, you must initially monitor for leaks within 30 days after August 12, 2020, or initial startup of the equipment, whichever is later. Equipment that is designated as unsafe- or difficult-to-monitor is not subject to this paragraph (b)(7).

(c) Except as specified in paragraphs (c)(10) and (11) of this section, if you comply with 40 CFR part 65, subpart F, you may elect to comply with the provisions in paragraphs (c)(1) through (9) of this section as an alternative to the referenced provisions in 40 CFR part 65, subpart F.

* * * * *

(5) Except as specified in paragraph (c)(10) of this section, for pumps in light liquid service in an MCPU that has no continuous process vents and is part of an existing source, you may elect to consider the leak definition that defines a leak to be 10,000 ppm or greater as an alternative to the values specified in § 65.107(b)(2)(i) through (iii) of this chapter.

* * * * *

(10) Beginning no later than the compliance dates specified in § 63.2445(h), paragraph (c)(5) of this section no longer applies.

(11) For each piece of equipment that is subject to Table 6 to this subpart and is also subject to periodic monitoring with EPA Method 21 of 40 CFR part 60, appendix A–7, and is added to an affected source after December 17, 2019, or replaces equipment at an affected source after December 17, 2019, you must initially monitor for leaks within 30 days after August 12, 2020, or initial startup of the equipment, whichever is later. Equipment that is designated as unsafe- or difficult-to-monitor is not subject to this paragraph (c)(11).

* * * * *

(e) Beginning no later than the compliance dates specified in § 63.2445(g), except as specified in paragraph (e)(4) of this section, you must comply with the requirements specified in paragraphs (e)(1) and (2) of this section for pressure relief devices, such as relief valves or rupture disks, in organic HAP gas or vapor service instead of the pressure relief device requirements of § 63.1030 of subpart UU, § 63.165 of subpart H, or § 65.111 of this chapter. Except as specified in paragraphs (e)(4) and (5) of this section, you must also comply with the requirements specified in paragraphs (e)(3), (6), (7), and (8) of this section for

all pressure relief devices in organic HAP service.

(1) *Operating requirements.* Except during a pressure release, operate each pressure relief device in organic HAP gas or vapor service with an instrument reading of less than 500 ppm above background as measured by the method in § 63.1023(b) of subpart UU, § 63.180(c) of subpart H, or § 65.104(b) of this chapter.

(2) *Pressure release requirements.* For pressure relief devices in organic HAP gas or vapor service, you must comply with the applicable requirements paragraphs (e)(2)(i) through (iii) of this section following a pressure release.

(i) If the pressure relief device does not consist of or include a rupture disk, conduct instrument monitoring, as specified in § 63.1023(b) of subpart UU, § 63.180(c) of subpart H, or § 65.104(b) of this chapter, no later than 5 calendar days after the pressure relief device returns to organic HAP gas or vapor service following a pressure release to verify that the pressure relief device is operating with an instrument reading of less than 500 ppm.

(ii) If the pressure relief device includes a rupture disk, either comply with the requirements in paragraph (e)(2)(i) of this section (and do not replace the rupture disk) or install a replacement disk as soon as practicable after a pressure release, but no later than 5 calendar days after the pressure release. You must conduct instrument monitoring, as specified in § 63.1023(b) of subpart UU, § 63.180(c) of subpart H, or § 65.104(b) of this chapter, no later than 5 calendar days after the pressure relief device returns to organic HAP gas or vapor service following a pressure release to verify that the pressure relief device is operating with an instrument reading of less than 500 ppm.

(iii) If the pressure relief device consists only of a rupture disk, install a replacement disk as soon as practicable after a pressure release, but no later than 5 calendar days after the pressure release. You must not initiate startup of the equipment served by the rupture disk until the rupture disc is replaced. You must conduct instrument monitoring, as specified in § 63.1023(b) of subpart UU, § 63.180(c) of subpart H, or § 65.104(b) of this chapter, no later than 5 calendar days after the pressure relief device returns to organic HAP gas or vapor service following a pressure release to verify that the pressure relief device is operating with an instrument reading of less than 500 ppm.

(3) *Pressure release management.* Except as specified in paragraphs (e)(4) and (5) of this section, you must comply with the requirements specified in paragraphs (e)(3)(i) through (v) of this section for all pressure relief devices in organic HAP service.

(i) You must equip each affected pressure relief device with a device(s) or use a monitoring system that is capable of:

(A) Identifying the pressure release;

(B) Recording the time and duration of each pressure release; and

(C) Notifying operators immediately that a pressure release is occurring. The device or monitoring system must be either specific to the pressure relief device itself or must be associated with the process system or piping, sufficient to indicate a pressure release to the atmosphere. Examples of these types of devices and systems include, but are not limited to, a rupture disk indicator, magnetic sensor, motion detector on the pressure relief valve stem, flow monitor, or pressure monitor.

(ii) You must apply at least three redundant prevention measures to each affected pressure relief device and document these measures. Examples of prevention measures include:

(A) Flow, temperature, liquid level and pressure indicators with deadman switches, monitors, or automatic actuators. Independent, non-duplicative systems within this category count as separate redundant prevention measures.

(B) Documented routine inspection and maintenance programs and/or operator training (maintenance programs and operator training may count as only one redundant prevention measure).

(C) Inherently safer designs or safety instrumentation systems.

(D) Deluge systems.

(E) Staged relief system where the initial pressure relief device (with lower set release pressure) discharges to a flare or other closed vent system and control device.

(iii) If any affected pressure relief device releases to atmosphere as a result of a pressure release event, you must perform root cause analysis and corrective action analysis according to the requirement in paragraph (e)(6) of this section and implement corrective actions according to the requirements in paragraph (e)(7) of this section. You must also calculate the quantity of organic HAP released during each pressure release event and report this quantity as required in § 63.2520(e)(15). Calculations may be based on data from the pressure relief device monitoring alone or in combination with process parameter monitoring data and process knowledge.

(iv) You must determine the total number of release events that occurred during the calendar year for each affected pressure relief device separately. You must also determine the total number of release events for each pressure relief device for which the root cause analysis concluded that the root cause was a *force majeure* event, as defined in § 63.2550.

(v) Except for pressure relief devices described in paragraphs (e)(4) and (5) of this section, the following release events from an affected pressure relief device are a deviation of the pressure release management work practice standards.

(A) Any release event for which the root cause of the event was determined to be operator error or poor maintenance.

(B) A second release event not including *force majeure* events from a single pressure relief device in a 3 calendar year period for the same root cause for the same equipment.

(C) A third release event not including *force majeure* events from a single pressure relief device in a 3 calendar year period for any reason.

(4) *Pressure relief devices routed to a control device, process, fuel gas system, or drain system.* (i) If all releases and potential leaks from a pressure relief device are routed through a closed vent system to a control device, back into the process, to the fuel gas system, or to a drain system, then you are not required to comply with paragraph (e)(1), (2), or (3) of this section.

(ii) Before the compliance dates specified in § 63.2445(g), both the closed vent system and control device (if applicable) referenced in paragraph (e)(4)(i) of this section must meet the applicable requirements specified in § 63.982(b) and (c)(2) of subpart SS. Beginning no later than the compliance dates specified in § 63.2445(g), both the closed vent system and control device (if applicable) referenced in paragraph (e)(4)(i) of this section must meet the applicable requirements specified in §§ 63.982(c)(2), 63.983, and 63.2450(e)(4) through (6).

(iii) The drain system (if applicable) referenced in paragraph (e)(4)(i) must meet the applicable requirements specified in § 63.2485(e).

(5) *Pressure relief devices exempted from pressure release management requirements.* The following types of pressure relief devices are not subject to the pressure release management requirements in paragraph (e)(3) of this section.

(i) Pressure relief devices in heavy liquid service, as defined in § 63.1020 of subpart UU or § 65.103(f) of this chapter.

(ii) Thermal expansion relief valves.

(iii) Pressure relief devices on mobile equipment.

(iv) Pilot-operated pressure relief devices where the primary release valve is routed through a closed vent system to a control device or back into the process, to the fuel gas system, or to a drain system.

(v) Balanced bellows pressure relief devices where the primary release valve is routed through a closed vent system to a control device or back into the process, to the fuel gas system, or to a drain system.

(6) *Root cause analysis and corrective action analysis.* A root cause analysis and corrective action analysis must be completed as soon as possible, but no later than 45 days after a release event. Special circumstances affecting the number of root cause analyses and/or corrective action analyses are provided in paragraphs (e)(6)(i) through (iii) of this section.

(i) You may conduct a single root cause analysis and corrective action analysis for a single emergency event that causes two or more pressure relief devices installed on the same equipment to release.

(ii) You may conduct a single root cause analysis and corrective action analysis for a single emergency event that causes two or more pressure relief devices to release, regardless of the equipment served, if the root cause is reasonably expected to be a *force majeure* event, as defined in § 63.2550.

(iii) Except as provided in paragraphs (e)(6)(i) and (ii) of this section, if more than one pressure relief device has a release during the same time period, an initial root cause analysis must be conducted separately for each pressure relief device that had a release. If the initial root cause analysis indicates that the release events have the same root cause(s), the initially separate root cause analyses may be recorded as a single root cause analysis and a single corrective action analysis may be conducted.

(7) *Corrective action implementation.* You must conduct a root cause analysis and corrective action analysis as specified in paragraphs (e)(3)(iii) and (e)(6) of this section, and you must implement the corrective action(s) identified in the corrective action analysis in accordance with the applicable requirements in paragraphs (e)(7)(i) through (iii) of this section.

(i) All corrective action(s) must be implemented within 45 days of the event for which the root cause and corrective action analyses were required or as soon thereafter as practicable. If you conclude that no corrective action should be implemented, you must record and explain the basis for that conclusion no later than 45 days following the event.

(ii) For corrective actions that cannot be fully implemented within 45 days following the event for which the root cause and corrective action analyses were required, you must develop an implementation schedule to complete the corrective action(s) as soon as practicable.

(iii) No later than 45 days following the event for which a root cause and corrective action analyses were required, you must record the corrective action(s) completed to date, and, for action(s) not already completed, a schedule for implementation, including proposed commencement and completion dates.

(8) *Flowing pilot-operated pressure relief devices.* For affected sources that commenced construction or reconstruction on or before December 17, 2019, you are prohibited from installing a flowing pilot-operated pressure relief device or replacing any pressure relief device with a flowing pilot-operated pressure relief device after August 12, 2023. For affected sources that commenced construction or reconstruction after December 17, 2019, you are prohibited from installing and operating flowing pilot-operated pressure relief devices. For purpose of compliance with this paragraph (e)(8), a flowing pilot-operated pressure relief device means the type of pilot-operated pressure relief device where the pilot discharge vent continuously releases emissions to the atmosphere when the pressure relief device is actuated.

(f) Beginning no later than the compliance dates specified in § 63.2445(g), the referenced provisions specified in paragraphs (f)(1) through (18) of this section do not apply when demonstrating compliance with this section.

(1) Section 63.163(c)(3) of subpart H.

(2) Section 63.172(j)(3) of subpart H.

(3) The second sentence of § 63.181(d)(5)(i) of subpart H.

(4) The phrase ''may be included as part of the startup, shutdown, and malfunction plan, as required by the referencing subpart for the source, or'' from § 63.1024(f)(4)(i) of subpart UU.

(5) Section 63.1026(b)(3) of subpart UU.

(6) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1026(e)(1)(ii)(A) of subpart UU.

(7) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1028(e)(1)(i)(A) of subpart UU.

(8) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1031(b)(1) of subpart UU.

(9) The second sentence of § 65.105(f)(4)(i) of this chapter.

(10) Section 65.107(b)(3) of this chapter.

(11) The phrase ''(except periods of start-up, shutdown, or malfunction)'' from § 65.107(e)(1)(ii)(A) of this chapter.

(12) The phrase ''(except during periods of start-up, shutdown, or malfunction)'' from § 65.109(e)(1)(i)(A) of this chapter.

(13) The phrase ''(except during periods of start-up, shutdown, or malfunction)'' from § 65.112(b)(1) of this chapter.

(14) The last sentence of § 65.115(b)(1) of this chapter.

(15) The last sentence of § 65.115(b)(2) of this chapter.

(16) The phrase ''Except for pressure relief devices needed for safety purposes, low leg drains, high point bleeds, analyzer vents, and open-ended valves or lines'' in § 65.143(a)(3) of this chapter.

(17) For flares complying with § 63.2450(e)(5), the following provisions do not apply:

(i) Section 63.172(d) of subpart H;

(ii) Section 63.180(e) of subpart H;

(iii) Section 63.181(g)(1)(iii) of subpart H;

(iv) The phrase ''including periods when a flare pilot light system does not have a flame'' from § 63.181(g)(2)(i) of subpart H;

(v) Section 63.1034(b)(2)(iii) of subpart UU; and

(vi) Section 65.115(b)(2) of this chapter.

(18) For pressure relief devices complying with § 63.2480(e), the following provisions are modified as follows:

(i) In the introductory text of § 63.180(c), replace the reference to § 63.165(a) with § 63.2480(e)(1).

(ii) In § 63.181(b)(2)(i), replace the reference to § 63.165(c) with § 63.2480(e)(4).

(iii) In § 63.181(b)(2)(i), replace the reference to § 63.165(a) with § 63.2480(e)(1).

(iv) In § 63.181(b)(3)(ii), replace the reference to § 63.165(d) with § 63.2480(e)(2)(ii) and (iii).

(v) In § 63.181(f), replace the reference to § 63.165(a) and (b) with § 63.2480(e)(1) and (2).

(vi) The information required to be reported under § 63.182(d)(2)(xiv) is now required to be reported under § 63.2520(e)(15)(i) through (iii).

(vii) The reference to § 63.1030(b) in § 63.1021(a) no longer applies.

(viii) In § 63.1022(b)(2), replace the reference to § 63.1030(d) with § 63.2480(e)(4).

(ix) In § 63.1022(b)(3), replace the reference to § 63.1030(e) with § 63.2480(e)(2)(ii).

(x) The reference to § 63.1030(c) in § 63.1022(a)(1)(v) no longer applies. Instead comply with the § 63.2480(e)(1) and (2).

(xi) In § 63.1023(c) introductory text and (c)(4), replace the reference to § 63.1030(b) with § 63.2480(e)(1).

(xii) In § 63.1038(c) replace the reference to § 63.1030(c)(3) with § 63.2480(e)(2).

(xiii) The information required to be reported under § 63.1039(b)(4) is now required to be reported under § 63.2520(e)(15)(i) and (ii).

(xiv) The reference to § 65.111(b) of this chapter in § 65.102(a) of this chapter no longer applies.

(xv) In § 65.103(b)(3) of this chapter, replace the reference to § 65.111(d) with § 63.2480(e)(4).

(xvi) In § 65.103(b)(4) of this chapter, replace the reference to § 63.111(e) with § 63.2480(e)(2)(ii).

(xvii) The reference to § 65.111(b) and (c) of this chapter in § 65.104(a)(1)(iv) of this chapter no longer applies. Instead comply with § 63.2480(e)(1) and (2).

(xviii) In § 65.104(c) introductory text and (c)(4) of this chapter, replace the reference to § 63.111(b) with § 63.2480(e)(1).

(xix) In § 65.119(c)(5) of this chapter, replace the reference to § 65.111(c)(3) with § 63.2480(e)(2) and replace the reference to § 65.111(e) with § 63.2480(e)(2)(ii) and (iii).

(xx) The information required to be reported under § 65.120(b)(4) of this chapter is now required to be reported under § 63.2520(e)(15)(i) and (ii).

■ 12. Section 63.2485 is amended by:
■ a. Revising paragraphs (a) and (f);
■ b. Adding paragraph (h)(4);
■ c. Revising paragraph (i)(2)(ii);
■ d. Adding paragraph (i)(2)(iii);
■ e. Revising paragraphs (k), the first sentence of (n)(2) introductory text, and (n)(2)(ii) and (n)(2)(iv)(A);
■ f. Adding paragraph (n)(2)(vii);
■ g. Revising paragraphs (n)(4) and (o); and
■ h. Adding paragraphs (p) and (q).

The revisions and additions read as follows:

§ 63.2485 What requirements must I meet for wastewater streams and liquid streams in open systems within an MCPU?

(a) *General.* You must meet each requirement in Table 7 to this subpart that applies to your wastewater streams and liquid streams in open systems within an MCPU, except as specified in paragraphs (b) through (q) of this section.

* * * * *

(f) *Closed-vent system requirements.* Except as specified in § 63.2450(e)(6), when § 63.148(k) refers to closed vent systems that are subject to the requirements of § 63.172, the requirements of either § 63.172 or § 63.1034 apply for the purposes of this subpart.

* * * * *

(h) * * *

(4) As an alternative to using EPA Method 624 of 40 CFR part 136, appendix A, as specified in § 63.144(b)(5)(i)(C), you may use ASTM D5790–95 (Reapproved 2012) (incorporated by reference, see § 63.14) for the analysis of total organic HAP in wastewater samples. If you choose to use ASTM D5790–95 (Reapproved 2012), then you must also use the sampling procedures of EPA Method 25D 40 CFR part 60, appendix A–7, or an equivalent method.

(i) * * *

(2) * * *

(ii) The transferee must treat the wastewater stream or residual in a biological treatment unit in accordance with the requirement in paragraph (i)(2)(iii) of this section and the requirements of §§ 63.138 and 63.145 and the requirements referenced therein.

(iii) Beginning no later than the compliance dates specified in § 63.2445(g), the requirement of § 63.145(a)(3) no longer applies. Instead, the transferee must comply with the conditions specified in § 63.2450(g)(6).

* * * * *

(k) *Outlet concentration correction for supplemental gases.* The requirement to correct outlet concentrations from combustion devices to 3-percent oxygen in §§ 63.139(c)(1)(ii) and 63.145(i)(6) applies only if supplemental gases are combined with a vent stream from a Group 1 wastewater stream. If emissions are controlled with a vapor recovery system as specified in § 63.139(c)(2), you must correct for supplemental gases as specified in § 63.2460(c)(6).

* * * * *

(n) * * *

(2) Calculate the destruction efficiency of the biological treatment unit using Equation 1 to this paragraph (n)(2) in accordance with the procedures described in paragraphs (n)(2)(i) through (viii) of this section. * * *

* * * * *

(ii) Except as specified in paragraph (n)(2)(vii) of this section, conduct the demonstration under representative process unit and treatment unit operating conditions in accordance with § 63.145(a)(3) and (4).

* * * * *

(iv) * * *

(A) If the biological treatment process meets both of the requirements specified in § 63.145(h)(1)(i) and (ii), you may elect to replace the F_{bio} term in Equation 1 to paragraph (n)(2) of this section with the numeral ''1.''

* * * * *

(vii) Beginning no later than the compliance dates specified in § 63.2445(g), the requirement of § 63.145(a)(3) no longer applies. Instead, you must comply with the conditions specified in § 63.2450(g)(6).

* * * * *

(4) For any wastewater streams that are Group 1 for both PSHAP and SHAP, you may elect to meet the requirements specified in Table 7 to this subpart for the PSHAP and then comply with paragraphs (n)(1) through (3) of this section for the SHAP in the wastewater system. You may determine the SHAP mass removal rate, in kg/hr, in treatment units that are used to meet the requirements for PSHAP and add this amount to both the numerator and denominator in Equation 1 to paragraph (n)(2) of this section.

(o) *Compliance records.* Except as specified in paragraph (p) of this section, for each CPMS used to monitor a nonflare control device for wastewater emissions, you must keep records as specified in § 63.998(c)(1) in addition to the records required in § 63.147(d).

(p) *Compliance records after date of compliance.* Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (o) of this section no longer applies. Instead, for each CPMS used to monitor a nonflare control device for wastewater emissions, you must keep records as specified in § 63.998(c)(1) in addition to the records required in § 63.147(d), except that the provisions of § 63.998(c)(1)(ii)(D), (E), (F), and (G) do not apply.

(q) *Startup, shutdown, and malfunction referenced provisions.* Beginning no later than the compliance dates specified in § 63.2445(g), the referenced provisions specified in paragraphs (q)(1) through (5) of this section do not apply when demonstrating compliance with this section.

(1) Section 63.105(d) of subpart F and the phrase ''as part of the start-up, shutdown, and malfunction plan required under § 63.6(e)(3) of subpart A of this part'' from § 63.105(e) of subpart F.

(2) Section 63.132(b)(3)(i)(B) of subpart G.

(3) The phrase ''or startup/shutdown/malfunction'' in § 63.132(f)(2) of subpart G.

(4) Section 63.148(f)(3) of subpart G.

(5) For flares complying with § 63.2450(e)(5), the following provisions do not apply:

(i) Section 63.139(c)(3) of subpart G;

(ii) Section 63.139(d)(3) of subpart G;

(iii) Section 63.145(j) of subpart G;

(iv) Section 63.146(b)(7)(i) of subpart G; and

(v) Section 63.147(d)(1) of subpart G.

■ 13. Section 63.2490 is revised to read as follows:

§ 63.2490 What requirements must I meet for heat exchange systems?

(a) You must comply with each requirement in Table 10 to this subpart that applies to your heat exchange systems, except as specified in paragraphs (b) through (d) of this section.

(b) Except as specified in paragraph (d) of this section, if you comply with the requirements of § 63.104 as specified in Table 10 to this subpart, then the phrase ''a chemical manufacturing process unit meeting the conditions of § 63.100 (b)(1) through (b)(3) of this subpart'' in § 63.104(a) means ''an MCPU meeting the conditions of § 63.2435'' for the purposes of this subpart.

(c) Except as specified in paragraph (d) of this section, if you comply with the requirements of § 63.104 as specified in Table 10 to this subpart, then the reference to ''§ 63.100(c)'' in § 63.104(a) does not apply for the purposes of this subpart.

(d) Unless one or more of the conditions specified in § 63.104(a)(1), (2), (5), and (6) are met, beginning no later than the compliance dates specified in § 63.2445(g), the requirements of § 63.104 as specified in Table 10 to this subpart and paragraphs (b) and (c) of this section no longer apply. Instead, you must monitor the cooling water for the presence of total strippable hydrocarbons that indicate a leak according to paragraph (d)(1) of this section, and if you detect a leak, then you must repair it according to paragraphs (d)(2) and (3) of this section, unless repair is delayed according to paragraph (d)(4) of this section. At any time before the compliance dates specified in § 63.2445(g), you may choose to comply with the requirements in this paragraph (d) in lieu of the requirements of § 63.104 as specified in Table 10 to this subpart and paragraphs (b) and (c) of this section. The requirements in this paragraph (d) do not apply to heat exchange systems that have a maximum cooling water flow rate of 10 gallons per minute or less.

(1) You must perform monitoring to identify leaks of total strippable hydrocarbons from each heat exchange system subject to the requirements of this subpart according to the procedures in paragraphs (d)(1)(i) through (v) of this section.

(i) *Monitoring locations for closed-loop recirculation heat exchange systems.* For each closed loop recirculating heat exchange system, you must collect and analyze a sample from the location(s) described in either paragraph (d)(1)(i)(A) or (B) of this section.

(A) Each cooling tower return line or any representative riser within the cooling tower prior to exposure to air for each heat exchange system.

(B) Selected heat exchanger exit line(s), so that each heat exchanger or group of heat exchangers within a heat exchange system is covered by the selected monitoring location(s).

(ii) *Monitoring locations for once-through heat exchange systems.* For each once-through heat exchange system, you must collect and analyze a sample from the location(s) described in paragraph (d)(1)(ii)(A) of this section. You may also elect to collect and analyze an additional sample from the location(s) described in paragraph (d)(1)(ii)(B) of this section.

(A) Selected heat exchanger exit line(s), so that each heat exchanger or group of heat exchangers within a heat exchange system is covered by the selected monitoring location(s). The selected monitoring location may be at a point where discharges from multiple heat exchange systems are combined provided that the combined cooling water flow rate at the monitoring location does not exceed 40,000 gallons per minute.

(B) The inlet water feed line for a once-through heat exchange system prior to any heat exchanger. If multiple heat exchange systems use the same water feed (*i.e.,* inlet water from the same primary water source), you may monitor at one representative location and use the monitoring results for that sampling location for all heat exchange systems that use that same water feed.

(iii) *Monitoring method.* If you comply with the total strippable hydrocarbon concentration leak action level as specified in paragraph (d)(1)(iv) of this section, you must comply with the requirements in paragraph (d)(1)(iii)(A) of this section. If you comply with the total hydrocarbon mass emissions rate leak action level as specified in paragraph (d)(1)(iv) of this section, you must comply with the requirements in paragraphs (d)(1)(iii)(A) and (B) of this section.

(A) You must determine the total strippable hydrocarbon concentration (in parts per million by volume (ppmv) as methane) at each monitoring location using the ''Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources'' (incorporated by reference—see § 63.14) using a flame ionization detector (FID) analyzer for on-site determination as described in Section 6.1 of the Modified El Paso Method.

(B) You must convert the total strippable hydrocarbon concentration (in ppmv as methane) to a total hydrocarbon mass emissions rate (as methane) using the calculations in Section 7.0 of ''Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources'' (incorporated by reference—see § 63.14).

(iv) *Monitoring frequency and leak action level.* For each heat exchange system, you must initially monitor monthly for 6-months beginning upon startup and monitor quarterly thereafter using a leak action level defined as a total strippable hydrocarbon concentration (as methane) in the stripping gas of 6.2 ppmv or, for heat exchange systems with a recirculation rate of 10,000 gallons per minute or less, you may monitor quarterly using a leak action level defined as a total hydrocarbon mass emissions rate from the heat exchange system (as methane) of 0.18 kg/hr. If a leak is detected as specified in paragraph (d)(1)(v) of this section, then you must monitor monthly until the leak has been repaired according to the requirements in paragraph (d)(2) or (3) of this section. Once the leak has been repaired according to the requirements in paragraph (d)(2) or (3) of this section, quarterly monitoring for the heat exchange system may resume. The monitoring frequencies specified in this paragraph (d)(1)(iv) also apply to the inlet water feed line for a once-through heat exchange system, if monitoring of the inlet water feed is elected as provided in paragraph (d)(1)(ii)(B) of this section.

(v) *Leak definition.* A leak is defined as described in paragraph (d)(1)(v)(A) or (B) of this section, as applicable.

(A) For once-through heat exchange systems for which the inlet water feed is monitored as described in paragraph (d)(1)(ii)(B) of this section, a leak is detected if the difference in the measurement value of the sample taken from a location specified in paragraph

(d)(1)(ii)(A) of this section and the measurement value of the corresponding sample taken from the location specified in paragraph (d)(1)(ii)(B) of this section equals or exceeds the leak action level.

(B) For all other heat exchange systems, a leak is detected if a measurement value of the sample taken from a location specified in paragraph (d)(1)(i)(A) or (B) or (d)(1)(ii)(A) of this section equals or exceeds the leak action level.

(2) If a leak is detected using the methods described in paragraph (d)(1) of this section, you must repair the leak to reduce the concentration or mass emissions rate to below the applicable leak action level as soon as practicable, but no later than 45 days after identifying the leak, except as specified in paragraph (d)(4) of this section. Repair must include re-monitoring at the monitoring location where the leak was identified according to the method specified in paragraph (d)(1)(iii) of this section to verify that the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate is below the applicable leak action level. Repair may also include performing the additional monitoring in paragraph (d)(3) of this section to verify that the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate is below the applicable leak action level. Actions that can be taken to achieve repair include but are not limited to:

(i) Physical modifications to the leaking heat exchanger, such as welding the leak or replacing a tube;

(ii) Blocking the leaking tube within the heat exchanger;

(iii) Changing the pressure so that water flows into the process fluid;

(iv) Replacing the heat exchanger or heat exchanger bundle; or

(v) Isolating, bypassing, or otherwise removing the leaking heat exchanger from service until it is otherwise repaired.

(3) If you detect a leak when monitoring a cooling tower return line under paragraph (d)(1)(i)(A) of this section, you may conduct additional monitoring of each heat exchanger or group of heat exchangers associated with the heat exchange system for which the leak was detected, as provided in paragraph (d)(1)(i)(B) of this section. If no leaks are detected when monitoring according to the requirements of paragraph (d)(1)(i)(B) of this section, the heat exchange system is considered to have met the repair requirements through re-monitoring of the heat exchange system, as provided in paragraph (d)(2) of this section.

(4) You may delay repair when one of the conditions in paragraph (d)(4)(i) or (ii) of this section is met and the leak is less than the delay of repair action level specified in paragraph (d)(4)(iii) of this section. You must determine if a delay of repair is necessary as soon as practicable, but no later than 45 days after first identifying the leak.

(i) If the repair is technically infeasible without a shutdown and the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate is initially and remains less than the delay of repair action level for all monitoring periods during the delay of repair, then you may delay repair until the next scheduled shutdown of the heat exchange system. If, during subsequent monitoring, the delay of repair action level is exceeded, then you must repair the leak within 30 days of the monitoring event in which the leak was equal to or exceeded the delay of repair action level.

(ii) If the necessary equipment, parts, or personnel are not available and the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate is initially and remains less than the delay of repair action level for all monitoring periods during the delay of repair, then you may delay the repair for a maximum of 120 calendar days. You must demonstrate that the necessary equipment, parts, or personnel were not available. If, during subsequent monitoring, the delay of repair action level is exceeded, then you must repair the leak within 30 days of the monitoring event in which the leak was equal to or exceeded the delay of repair action level.

(iii) The delay of repair action level is a total strippable hydrocarbon concentration (as methane) in the stripping gas of 62 ppmv or, for heat exchange systems with a recirculation rate of 10,000 gallons per minute or less, the delay of repair action level is a total hydrocarbon mass emissions rate (as methane) or 1.8 kg/hr. The delay of repair action level is assessed as described in paragraph (d)(4)(iii)(A) or (B) of this section, as applicable.

(A) For once-through heat exchange systems for which the inlet water feed is monitored as described in paragraph (d)(1)(ii)(B) of this section, the delay of repair action level is exceeded if the difference in the measurement value of the sample taken from a location specified in paragraph (d)(1)(ii)(A) of this section and the measurement value of the corresponding sample taken from the location specified in paragraph (d)(1)(ii)(B) of this section equals or exceeds the delay of repair action level.

(B) For all other heat exchange systems, the delay of repair action level is exceeded if a measurement value of the sample taken from a location specified in paragraph (d)(1)(i)(A) or (B) or (d)(1)(ii)(A) of this section equals or exceeds the delay of repair action level.

■ 14. Section 63.2492 is added to read as follows:

§ 63.2492 How do I determine whether my process vent, storage tank, or equipment is in ethylene oxide service?

To determine if process vents, storage tanks, and equipment leaks are in ethylene oxide service as defined in § 63.2550(i), you must comply with the requirements in paragraphs (a) through (c) of this section, as applicable.

(a) For each batch process vent or continuous process vent stream, you must measure the flow rate and concentration of ethylene oxide of each process vent as specified in paragraphs (a)(1) through (5) of this section.

(1) Measurements must be made prior to any dilution of the vent streams.

(2) Measurements may be made on the combined vent streams at an MCPU or for each separate vent stream.

(3) Method 1 or 1A of 40 CFR part 60, appendix A–1, as appropriate, must be used for the selection of the sampling sites. For vents smaller than 0.10 meter in diameter, sample at one point at the center of the duct.

(4) The gas volumetric flow rate must be determined using Method 2, 2A, 2C, 2D, 2F, or 2G of 40 CFR part 60, appendices A–1 and A–2, as appropriate.

(5) The concentration of ethylene oxide must be determined using Method 18 of 40 CFR part 60, appendix A–6, or Method 320 of appendix A to this part.

(b) For storage tanks, you must measure the concentration of ethylene oxide of the fluid stored in the storage tanks using Method 624.1 of 40 CFR part 136, appendix A, or preparation by Method 5031 and analysis by Method 8260D (both incorporated by reference, see § 63.14) in the SW–846 Compendium. In lieu of preparation by SW–846 Method 5031, you may use SW–846 Method 5030B (incorporated by reference, see § 63.14), as long as: You do not use a preservative in the collected sample; you store the sample with minimal headspace as cold as possible and at least below 4 degrees C; and you analyze the sample as soon as possible, but in no case longer than 7 days from the time the sample was collected. If you are collecting a sample from a pressure vessel, you must maintain the sample under pressure both during and following sampling.

(c) For equipment leaks, you must comply with the requirements in paragraphs (c)(1) through (4) of this section.

(1) Each piece of equipment within an MCPU that can reasonably be expected to contain equipment in ethylene oxide service is presumed to be in ethylene oxide service unless you demonstrate that the piece of equipment is not in ethylene oxide service. For a piece of equipment to be considered not in ethylene oxide service, it must be determined that the percent ethylene oxide content of the process fluid that is contained in or contacts equipment can be reasonably expected to not exceed 0.1 percent by weight on an annual average basis. For purposes of determining the percent ethylene oxide content of the process fluid, you must use Method 18 of 40 CFR part 60, appendix A–6, for gaseous process fluid, and Method 624.1 of 40 CFR part 136, appendix A, or preparation by Method 5031 and analysis by Method 8260D (both incorporated by reference, see § 63.14) in the SW–846 Compendium for liquid process fluid. In lieu of preparation by SW–846 Method 5031, you may use SW–846 Method 5030B (incorporated by reference, see § 63.14), as long as: You do not use a preservative in the collected sample; you store the sample with minimal headspace as cold as possible and at least below 4 degrees C; and you analyze the sample as soon as possible, but in no case longer than 7 days from the time the sample was collected.

(2) Unless specified by the Administrator, you may use good engineering judgment rather than the procedures specified in paragraph (c)(1) of this section to determine that the percent ethylene oxide content of the process fluid that is contained in or contacts equipment does not exceed 0.1 percent by weight.

(3) You may revise your determination for whether a piece of equipment is in ethylene oxide service by following the procedures in paragraph (c)(1) of this section, or by documenting that a change in the process or raw materials no longer causes the equipment to be in ethylene oxide service.

(4) Samples used in determining the ethylene oxide content must be representative of the process fluid that is contained in or contacts the equipment.

■ 15. Section 63.2493 is added to read as follows:

§ 63.2493 What requirements must I meet for process vents, storage tanks, or equipment that are in ethylene oxide service?

This section applies beginning no later than the compliance dates specified in § 63.2445(i). In order to demonstrate compliance with the emission limits and work practice standards specified in Tables 1, 2, and 4 to this subpart for process vents and storage tanks in ethylene oxide service, you must meet the requirements specified in paragraphs (a) through (c) of this section. In order to demonstrate compliance with the requirements specified in Table 6 to this subpart for equipment in ethylene oxide service, you must meet the requirements specified in paragraphs (d) and (e) of this section.

(a) *Initial compliance.* For initial compliance, you must comply with paragraphs (a)(1) through (4) of this section, as applicable.

(1) If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a flare as specified in Table 1, 2, or 4 to this subpart, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must conduct the initial visible emissions demonstration required by § 63.670(h) of subpart CC as specified in § 63.2450(e)(5).

(2) If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a non-flare control device that reduces ethylene oxide by greater than or equal to 99.9 percent by weight as specified in Table 1, 2, or 4 to this subpart, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must comply with paragraphs (a)(2)(i) through (viii) of this section.

(i) Conduct an initial performance test of the control device that is used to comply with the percent reduction requirement at the inlet and outlet of the control device. For purposes of compliance with this paragraph (a)(2), you may not use a design evaluation.

(ii) Conduct the performance test according to the procedures in §§ 63.997 and 63.2450(g). Use Method 18 of 40 CFR part 60, appendix A–6, or Method 320 of appendix A to this part to determine the ethylene oxide concentration. Use Method 1 or 1A of 40 CFR part 60, appendix A–1, to select the sampling sites at each sampling location. Determine the gas volumetric flowrate using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A–2. Use Method 4 of 40 CFR part 60, appendix A–3, to convert the volumetric flowrate to a dry basis.

(iii) Calculate the mass emission rate of ethylene oxide entering the control device and exiting the control device using Equations 1 and 2 to this paragraph (a)(2)(iii).

$$E_{EtO,inlet} = K\ C_{EtO,inlet}\ M_{EtO}\ Q_{inlet} \quad \text{(Eq. 1)}$$

$$E_{EtO,outlet} = K\ C_{EtO,outlet}\ M_{EtO}\ Q_{outlet} \quad \text{(Eq. 2)}$$

Where:

$E_{EtO,inlet}$, $E_{EtO,outlet}$ = Mass rate of ethylene oxide at the inlet and outlet of the control device, respectively, kilogram per hour.

$C_{EtO,inlet}$, $C_{EtO,outlet}$ = Concentration of ethylene oxide in the gas stream at the inlet and outlet of the control device, respectively, dry basis, parts per million by volume.

M_{EtO} = Molecular weight of ethylene oxide, 44.05 grams per gram-mole.

Q_{inlet}, Q_{outlet} = Flow rate of the gas stream at the inlet and outlet of the control device, respectively, dry standard cubic meter per minute.

K = Constant, $2.494 \times 10-6$ (parts per million) -1 (gram-mole per standard cubic meter) (kilogram per gram) (minutes per hour), where standard temperature (gram-mole per standard cubic meter) is 20 °C.

(iv) Calculate the percent reduction from the control device using Equation 3 to this paragraph (a)(2)(iv). You have demonstrated initial compliance if the overall reduction of ethylene oxide is greater than or equal to 99.9 percent by weight.

$$\text{Percent reduction} = (E_{EtO,inlet} - E_{EtO,outlet})/E_{EtO,inlet} * 100 \quad \text{(Eq. 3)}$$

Where:

$E_{EtO,inlet}$, $E_{EtO,outlet}$ = Mass rate of ethylene oxide at the inlet and outlet of the control device, respectively, kilogram per hour, calculated using Equations 1 and 2 to paragraph (a)(2)(iii) of this section.

(v) If a new control device is installed, then conduct a performance test of the new device following the procedures in paragraphs (a)(2)(i) through (iv) of this section.

(vi) If you vent emissions through a closed-vent system to a scrubber, then you must establish operating parameter limits by monitoring the operating parameters specified in paragraphs (a)(2)(vi)(A) through (C) of this section during the performance test.

(A) Scrubber liquid-to-gas ratio (L/G), determined from the total scrubber liquid inlet flow rate and the exit gas flow rate. Determine the average L/G during the performance test as the average of the test run averages.

(B) Scrubber liquid pH of the liquid in the reactant tank. The pH may be measured at any point between the discharge from the scrubber column and the inlet to the reactant tank. Determine the average pH during the performance test as the average of the test run averages.

(C) Temperature of the water entering the scrubber column. The temperature may be measured at any point after the heat exchanger and prior to entering the top of the scrubber column. Determine the average inlet water temperature as the average of the test run averages.

(vii) If you vent emissions through a closed-vent system to a thermal oxidizer, then you must establish operating parameter limits by monitoring the operating parameters specified in paragraphs (a)(2)(vii)(A) and (B) of this section during the performance test.

(A) Combustion chamber temperature. Determine the average combustion chamber temperature during the performance test as the average of the test run averages.

(B) Flue gas flow rate. Determine the average flue gas flow rate during the performance test as the average of the test run averages.

(viii) If you vent emissions through a closed-vent system to a control device other than a flare, scrubber, or thermal oxidizer, then you must notify the Administrator of the operating parameters that you plan to monitor during the performance test prior to establishing operating parameter limits for the control device.

(3) If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a non-flare control device that reduces ethylene oxide to less than 1 ppmv as specified in Table 1, 2, or 4 to this subpart, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must comply with either paragraph (a)(3)(i) or (ii) of this section.

(i) Install an FTIR CEMS meeting the requirements of Performance Specification 15 of 40 CFR part 60, appendix B, to continuously monitor the ethylene oxide concentration at the exit of the control device. Comply with the requirements specified in § 63.2450(j) for your CEMS.

(ii) If you do not install a CEMS under paragraph (a)(3)(i) of this section, you must comply with paragraphs (a)(3)(ii)(A) through (C) of this section.

(A) Conduct an initial performance test of the control device that is used to comply with the concentration requirement at the outlet of the control device.

(B) Conduct the performance test according to the procedures in §§ 63.997 and 63.2450(g). Use Method 18 of 40 CFR part 60, appendix A–6, or Method 320 of appendix A to this part to determine the ethylene oxide concentration. You have demonstrated initial compliance if the ethylene oxide concentration is less than 1 ppmv.

(C) Comply with the requirements specified in paragraphs (a)(2)(v) through (viii) of this section, as applicable.

(4) If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a non-flare control device that reduces ethylene oxide to less than 5 pounds per year for all combined process vents as specified in Table 1 or 2 to this subpart, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must comply with paragraphs (a)(4)(i) through (iv) of this section.

(i) Conduct an initial performance test of the control device that is used to comply with the mass emission limit requirement at the outlet of the control device.

(ii) Conduct the performance test according to the procedures in §§ 63.997 and 63.2450(g). Use Method 18 of 40 CFR part 60, appendix A–6, or Method 320 of appendix A to this part to determine the ethylene oxide concentration. Use Method 1 or 1A of 40 CFR part 60, appendix A–1, to select the sampling site. Determine the gas volumetric flowrate using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A–2. Use Method 4 of 40 CFR part 60, appendix A–3, to convert the volumetric flowrate to a dry basis.

(iii) Calculate the mass emission rate of ethylene oxide exiting the control device using Equation 2 to paragraph (a)(2)(iii) of this section. You have demonstrated initial compliance if the ethylene oxide from all process vents (controlled and uncontrolled) is less than 5 pounds per year when combined.

(iv) Comply with the requirements specified in paragraphs (a)(2)(v) through (viii) of this section, as applicable.

(b) *Continuous compliance.* For continuous compliance, you must comply with paragraphs (b)(1) through (6) of this section, as applicable.

(1) If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a flare as specified in Table 1, 2, or 4 to this subpart, then you must comply with the requirements in §§ 63.983 and 63.2450(e)(4) through (6).

(2) Continuously monitor the ethylene oxide concentration at the exit of the control device using an FTIR CEMS meeting the requirements of Performance Specification 15 of 40 CFR part 60, appendix B, and § 63.2450(j). If you use an FTIR CEMS, you do not need to conduct the performance testing required in paragraph (b)(3) of this section or the operating parameter monitoring required in paragraphs (b)(4) through (6) of this section.

(3) Conduct a performance test no later than 60 months after the previous performance test and reestablish operating parameter limits following the procedures in paragraph (a)(2) through (4) of this section. The Administrator may request a repeat performance test at any time. For purposes of compliance with this paragraph (b)(3), you may not use a design evaluation.

(4) If you vent emissions through a closed-vent system to a scrubber, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must meet the operating parameter limits specified in paragraphs (b)(4)(i) through (v) of this section.

(i) Minimum scrubber liquid-to-gas ratio (L/G), equal to the average L/G measured during the most recent performance test. Determine total scrubber liquid inlet flow rate with a flow sensor with a minimum accuracy of at least ±5 percent over the normal range of flow measured, or 1.9 liters per minute (0.5 gallons per minute), whichever is greater. Determine exit gas flow rate with a flow sensor with a minimum accuracy of at least ±5 percent over the normal range of flow measured, or 280 liters per minute (10 cubic feet per minute), whichever is greater. Compliance with the minimum L/G operating limit must be determined continuously on a 1-hour block basis.

(ii) Maximum scrubber liquid pH of the liquid in the reactant tank, equal to the average pH measured during the most recent performance test. Compliance with the pH operating limit must be determined continuously on a 1-hour block basis. Use a pH sensor with a minimum accuracy of ±0.2 pH units.

(iii) Pressure drop across the scrubber column, within the pressure drop range specified by the manufacturer or established based on engineering analysis. Compliance with the pressure drop operating limit must be determined continuously on a 1-hour block basis. Use pressure sensors with a minimum accuracy of ±5 percent over the normal operating range or 0.12 kilopascals, whichever is greater.

(iv) Maximum temperature of the water entering the scrubber column, equal to the average temperature measured during the most recent performance test. Compliance with the inlet water temperature operating limit must be determined continuously on a 1-hour block basis. Use a temperature sensor with a minimum accuracy of ±1 percent over the normal range of the temperature measured, expressed in

degrees Celsius, or 2.8 degrees Celsius, whichever is greater.

(v) Liquid feed pressure to the scrubber column within the feed pressure range specified by the manufacturer or established based on engineering analysis. Compliance with the liquid feed pressure operating limit must be determined continuously on a 1-hour block basis. Use a pressure sensor with a minimum accuracy of ±5 percent over the normal operating range or 0.12 kilopascals, whichever is greater.

(5) If you vent emissions through a closed-vent system to a thermal oxidizer, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must meet the operating parameter limits specified in paragraphs (b)(5)(i) and (ii) of this section and the requirements in paragraph (b)(5)(iii) of this section.

(i) Minimum combustion chamber temperature, equal to the average combustion chamber temperature measured during the most recent performance test. Determine combustion chamber temperature with a temperature sensor with a minimum accuracy of at least ±1 percent over the normal range of temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. Compliance with the minimum combustion chamber temperature operating limit must be determined continuously on a 1-hour block basis.

(ii) Maximum flue gas flow rate, equal to the average flue gas flow rate measured during the most recent performance test. Determine flue gas flow rate with a flow sensor with a minimum accuracy of at least ±5 percent over the normal range of flow measured, or 280 liters per minute (10 cubic feet per minute), whichever is greater. Compliance with the maximum flue gas flow rate operating limit must be determined continuously on a 1-hour block basis.

(iii) You must maintain the thermal oxidizer in accordance with good combustion practices that ensure proper combustion. Good combustion practices include, but are not limited to, proper burner maintenance, proper burner alignment, proper fuel to air distribution and mixing, routine inspection, and preventative maintenance.

(6) If you vent emissions through a closed-vent system to a control device other than a flare, scrubber, or thermal oxidizer, then you must comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983, and you must monitor the operating parameters identified in paragraph (a)(2)(viii) of this section and meet the established operating parameter limits to ensure continuous compliance. The frequency of monitoring and averaging time will be determined based upon the information provided to the Administrator.

(c) *Pressure vessels.* If you have a storage tank in ethylene oxide service that is considered a pressure vessel as defined in as defined in § 63.2550(i), then you must operate and maintain the pressure vessel, as specified in paragraphs (c)(1) through (5) of this section.

(1) The pressure vessel must be designed to operate with no detectable emissions at all times.

(2) Monitor each point on the pressure vessel through which ethylene oxide could potentially be emitted by conducting initial and annual performance tests using Method 21 of 40 CFR part 60, appendix A–7.

(3) Each instrument reading greater than 500 ppmv is a deviation.

(4) Estimate the flow rate and total regulated material emissions from the defect. Assume the pressure vessel has been emitting for half of the time since the last performance test, unless other information supports a different assumption.

(5) Whenever ethylene oxide is in the pressure vessel, you must operate the pressure vessel as a closed system that vents through a closed vent system to a control device as specified in paragraphs (c)(5)(i) through (iii) of this section, as applicable.

(i) For closed vent systems, comply with § 63.2450(e)(4) and (6) and the requirements in § 63.983.

(ii) For a non-flare control device, comply with requirements as specified in paragraph (b) of this section.

(iii) For a flare, comply with the requirements of § 63.2450(e)(5).

(d) *Equipment in ethylene oxide service.* Except as specified in paragraphs (d)(1) through (4) and (e) of this section, for equipment in ethylene oxide service as defined in § 63.2550(i), you must comply with the requirements of subpart UU or H of this part, or 40 CFR part 65, subpart F.

(1) For pumps in ethylene oxide service, you must comply with the requirements in paragraphs (d)(1)(i) through (iii) of this section.

(i) The instrument reading that defines a leak for pumps is 1,000 parts per million or greater.

(ii) The monitoring period for pumps is monthly.

(iii) When a leak is detected, it must be repaired as soon as practicable, but not later than 15 calendar days after it is detected.

(2) For connectors in ethylene oxide service, you must comply with the requirements in paragraphs (d)(2)(i) through (iii) of this section.

(i) The instrument reading that defines a leak for connectors is 500 parts per million or greater.

(ii) The monitoring period for connectors is once every 12 months.

(iii) When a leak is detected, it must be repaired as soon as practicable, but not later than 15 calendar days after it is detected.

(3) For each light liquid pump or connector in ethylene oxide service that is added to an affected source, and for each light liquid pump or connector in ethylene oxide service that replaces a light liquid pump or connector in ethylene oxide service, you must initially monitor for leaks within 5 days after initial startup of the equipment.

(4) Pressure relief devices in ethylene oxide service must comply with the requirements in § 63.2480(e) and (f), except as specified in paragraphs (d)(4)(i) through (v) of this section.

(i) The second sentence in § 63.2480(e)(3)(iv) does not apply.

(ii) Section 63.2480(e)(3)(v) does not apply.

(iii) Section 63.2480(e)(6)(ii) does not apply.

(iv) Any release event from an affected pressure relief device is a deviation of the pressure release management work practice standards.

(v) Replace all references to § 63.2445(g) with § 63.2445(h).

(e) *Non-applicable referenced provisions.* The referenced provisions specified in paragraphs (e)(1) through (15) of this section do not apply when demonstrating compliance with this section.

(1) Section 63.163(c)(3) of subpart H.

(2) Section 63.163(e) of subpart H.

(3) The second sentence of § 63.181(d)(5)(i) of subpart H.

(4) Section 63.1026(b)(3) of subpart UU.

(5) Section 63.1026(e) of subpart UU.

(6) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1028(e)(1)(i)(A) of subpart UU.

(7) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1031(b)(1) of subpart UU.

(8) The second sentence of § 65.105(f)(4)(i) of this chapter.

(9) Section 65.107(b)(3) of this chapter.

(10) Section 65.107(e) of this chapter.

(11) The phrase ''(except during periods of start-up, shutdown, or malfunction)'' from § 65.109(e)(1)(i)(A) of this chapter.

(12) The phrase ''(except during periods of start-up, shutdown, or

malfunction)'' from § 65.112(b)(1) of this chapter.

(13) The last sentence of § 65.115(b)(1) of this chapter.

(14) The last sentence of § 65.115(b)(2) of this chapter.

(15) For flares complying with § 63.2450(e)(5), the following provisions do not apply:

(i) Section 63.172(d) of subpart H;

(ii) Section 63.180(e) of subpart H;

(iii) Section 63.181(g)(1)(iii) of subpart H;

(iv) The phrase ''including periods when a flare pilot light system does not have a flame'' from § 63.181(g)(2)(i) of subpart H;

(v) Section 63.1034(b)(2)(iii) of subpart H; and

(vi) Section 65.115(b)(2) of this chapter.

(16) Requirements for maintenance vents in § 63.2450(v).

■ 16. Section 63.2495 is amended by revising paragraph (b)(1) to read as follows:

§ 63.2495 How do I comply with the pollution prevention standard?

* * * * *

(b) * * *

(1) You must comply with the emission limitations and work practice standards contained in Tables 1 through 7 to this subpart for all HAP that are generated in the MCPU and that are not included in consumption, as defined in § 63.2550. If any vent stream routed to the combustion control is a halogenated vent stream, as defined in § 63.2550, then hydrogen halides that are generated as a result of combustion control must be controlled according to the requirements in § 63.2450(e)(4) and the requirements of § 63.994 and the requirements referenced therein.

* * * * *

■ 17. Section 63.2500 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 63.2500 How do I comply with emissions averaging?

(a) For an existing source, you may elect to comply with the percent reduction emission limitations in Tables 1, 2, 4, 5, and 7 to this subpart by complying with the emissions averaging provisions specified in § 63.150, except as specified in paragraphs (b) through (g) of this section.

* * * * *

(g) Beginning no later than the compliance dates specified in § 63.2445(g), § 63.150(f)(2) does not apply when demonstrating compliance with this section.

■ 18. Section 63.2505 is amended by revising paragraphs (b)(1) and (b)(6)(i) and (ii) to read as follows:

§ 63.2505 How do I comply with the alternative standard?

* * * * *

(b) * * *

(1) You must comply with the requirements in § 63.2450(e)(4) and (6), and the requirements in § 63.983 and the requirements referenced therein for closed-vent systems, except if you are not reducing organic HAP emissions by venting emissions through a closed-vent system to any combination of control devices, including a flare or recovery device, you are not required to comply with the requirements in § 63.983(b)(1)(i)(A), (b)(1)(ii), (c), (d)(1)(ii), and (d)(2) and (3).

* * * * *

(6) * * *

(i) Demonstrate initial compliance with the 95-percent reduction by conducting a performance test and setting a site-specific operating limit(s) for the scrubber in accordance with the requirements in § 63.2450(e)(4) and the requirements of § 63.994 and the requirements referenced therein. You must submit the results of the initial compliance demonstration in the notification of compliance status report. If the performance test report is submitted electronically through the EPA's CEDRI in accordance with § 63.2520(f), the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted may be submitted in the notification of compliance status report in lieu of the performance test results. The performance test results must be submitted to CEDRI by the date the notification of compliance status report is submitted.

(ii) Install, operate, and maintain CPMS for the scrubber as specified in §§ 63.994(c) and 63.2450(k), instead of as specified in § 63.1258(b)(5)(i)(C). You must also comply with the requirements in § 63.2450(e)(4), as applicable.

* * * * *

■ 19. Section 63.2515 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 63.2515 What notifications must I submit and when?

(a) *General.* Except as specified in paragraph (d) of this section, you must submit all of the notifications in §§ 63.6(h)(4) and (5), 63.7(b) and (c), 63.8(e) and (f)(4) and (6), and 63.9(b) through (h) of subpart A that apply to you by the dates specified.

* * * * *

(d) *Supplement to Notification of Compliance Status.* You must also submit supplements to the Notification of Compliance Status as specified in § 63.2520(d)(3) through (5).

■ 20. Section 63.2520 is amended by:

■ a. Revising paragraphs (c) introductory text and (c)(2);

■ b. Adding paragraph (c)(8);

■ c. Revising paragraphs (d) introductory text and (d)(2)(ii);

■ d. Adding paragraphs (d)(3) through (5);

■ e. Revising paragraphs (e) introductory text, (e)(2) through (4), (e)(5)(ii) introductory text, and (e)(5)(ii)(A) and (B);

■ f. Adding paragraph (e)(5)(ii)(D);

■ g. Revising paragraphs (e)(5)(iii) introductory text and (e)(5)(iii)(A) through (F) and (I);

■ h. Adding paragraphs (e)(5)(iii)(M) and (N);

■ i. Revising paragraphs (e)(7), (8), and (9);

■ j. Revising paragraphs (e)(10) introductory text and (e)(10)(i); and

■ k. Adding paragraphs (e)(11) through (17) and (f) through (i).

The revisions and additions read as follows:

§ 63.2520 What reports must I submit and when?

* * * * *

(c) *Precompliance report.* You must submit a precompliance report to request approval for any of the items in paragraphs (c)(1) through (8) of this section. We will either approve or disapprove the report within 90 days after we receive it. If we disapprove the report, you must still be in compliance with the emission limitations and work practice standards in this subpart by the compliance date. To change any of the information submitted in the report, you must notify us 60 days before the planned change is to be implemented.

* * * * *

(2) Descriptions of daily or per batch demonstrations to verify that control devices subject to § 63.2450(k)(6) are operating as designed.

* * * * *

(8) For halogen reduction device other than a scrubber, procedures for establishing monitoring parameters as required by § 63.2450(e)(3)(ii).

(d) *Notification of compliance status report.* You must submit a notification of compliance status report according to the schedule in paragraph (d)(1) of this section, and the notification of compliance status report must contain the information specified in paragraphs (d)(2) through (5) of this section.

* * * * *

(2) * * *

(ii) The results of emissions profiles, performance tests, engineering analyses, design evaluations, flare compliance assessments, inspections and repairs, and calculations used to demonstrate initial compliance according to §§ 63.2455 through 63.2485. For performance tests, results must include descriptions of sampling and analysis procedures and quality assurance procedures. If the performance test report is submitted electronically through the EPA's CEDRI in accordance with paragraph (f) of this section, the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted may be submitted in the notification of compliance status report in lieu of the performance test results. The performance test results must be submitted to CEDRI by the date the notification of compliance status report is submitted.

* * * * *

(3) For flares subject to the requirements of § 63.2450(e)(5), you must also submit the information in this paragraph (d)(3) in a supplement to the Notification of Compliance Status within 150 days after the first applicable compliance date for flare monitoring. In lieu of the information required in § 63.987(b) of subpart SS, the supplement to the Notification of Compliance Status must include flare design (*e.g.,* steam-assisted, air-assisted, non-assisted, or pressure-assisted multi-point); all visible emission readings, heat content determinations, flow rate measurements, and exit velocity determinations made during the initial visible emissions demonstration required by § 63.670(h) of subpart CC, as applicable; and all periods during the compliance determination when the pilot flame or flare flame is absent.

(4) For pressure relief devices subject to the pressure release management work practice standards in § 63.2480(e)(3), you must also submit the information listed in paragraphs (d)(4)(i) and (ii) of this section in a supplement to the Notification of Compliance Status within 150 days after the first applicable compliance date for pressure relief device monitoring.

(i) A description of the monitoring system to be implemented, including the relief devices and process parameters to be monitored, and a description of the alarms or other methods by which operators will be notified of a pressure release.

(ii) A description of the prevention measures to be implemented for each affected pressure relief device.

(5) For process vents, storage tanks, and equipment leaks subject to the requirements of § 63.2493, you must also submit the information in this paragraph (d)(5) in a supplement to the Notification of Compliance Status within 150 days after the first applicable compliance date. The supplement to the Notification of Compliance Status must identify all process vents, storage tanks, and equipment that are in ethylene oxide service as defined in § 63.2550, the method(s) used to control ethylene oxide emissions from each process vent and storage tank (*i.e.,* use of a flare, scrubber, or other control device), the method(s) used to control ethylene oxide emissions from equipment (*i.e.,* subpart UU or H of this part, or 40 CFR part 65, subpart F), and the information specified in paragraphs (d)(5)(i) through (iii) of this section.

(i) For process vents, include all uncontrolled, undiluted ethylene oxide concentration measurements, and the calculations you used to determine the total uncontrolled ethylene oxide mass emission rate for the sum of all vent gas streams.

(ii) For storage tanks, include the concentration of ethylene oxide of the fluid stored in each storage tank.

(iii) For equipment, include the percent ethylene oxide content of the process fluid and the method used to determine it.

(e) *Compliance report.* The compliance report must contain the information specified in paragraphs (e)(1) through (17) of this section. On and after August 12, 2023 or once the reporting template for this subpart has been available on the CEDRI website for 1 year, whichever date is later, you must submit all subsequent reports to the EPA via the CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed to be CBI. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. Unless the Administrator or delegated state agency or other authority has approved a different schedule for submission of reports under §§ 63.9(i) and 63.10(a) of subpart A, the report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, CORE CBI Office, U.S. EPA Mailroom (C404–02), Attention: Miscellaneous Organic Chemical Manufacturing Sector Lead, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in this paragraph (e). All CBI claims must be asserted at the time of submission. Furthermore under CAA section 114(c) emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. You may assert a claim of EPA system outage or *force majeure* for failure to timely comply with the reporting requirement in this paragraph (e) provided you meet the requirements outlined in paragraph (i) or (j) of this section, as applicable.

* * * * *

(2) Statement by a responsible official with that official's name, title, and signature, certifying the accuracy of the content of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces the requirement in this paragrpah (e)(2).

(3) Date of report and beginning and ending dates of the reporting period. You are no longer required to provide the date of report when the report is submitted via CEDRI.

(4) For each SSM during which excess emissions occur, the compliance report must include records that the procedures specified in your startup, shutdown, and malfunction plan (SSMP) were followed or documentation of actions taken that are not consistent with the SSMP, and include a brief description of each malfunction. On and after August 12, 2023, this paragraph (e)(4) no longer

applies; however, for historical compliance purposes, a copy of the plan must be retained and available on-site for five years after August 12, 2023.

(5) * * *

(ii) For each deviation from an emission limit, operating limit, and work practice standard that occurs at an affected source where you are not using a continuous monitoring system (CMS) to comply with the emission limit or work practice standard in this subpart, you must include the information in paragraphs (e)(5)(ii)(A) through (D) of this section. This includes periods of SSM.

(A) The total operating time in hours of the affected source during the reporting period.

(B) Except as specified in paragraph (e)(5)(ii)(D) of this section, information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

* * * * *

(D) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (e)(5)(ii)(B) of this section no longer applies. Instead, report information for each deviation to meet an applicable standard. For each instance, report the start date, start time, and duration in hours of each deviation. For each deviation, the report must include a list of the affected sources or equipment, an estimate of the quantity in pounds of each regulated pollutant emitted over any emission limit, a description of the method used to estimate the emissions, the cause of the deviation (including unknown cause, if applicable), as applicable, and the corrective action taken.

(iii) For each deviation from an emission limit or operating limit occurring at an affected source where you are using a CMS to comply with an emission limit in this subpart, you must include the information in paragraphs (e)(5)(iii)(A) through (N) of this section. This includes periods of SSM.

(A) The start date, start time, and duration in hours that each CMS was inoperative, except for zero (low-level) and high-level checks.

(B) The start date, start time, and duration in hours that each CEMS was out-of-control and a description of the corrective actions taken.

(C) Except as specified in paragraph (e)(5)(iii)(M) of this section, the date and time that each deviation started and stopped, and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(D) The total duration in hours of all deviations for each CMS during the reporting period, the total operating time in hours of the affected source during the reporting period, and the total duration as a percent of the total operating time of the affected source during that reporting period.

(E) Except as specified in paragraph (e)(5)(iii)(N) of this section, a breakdown of the total duration of the deviations during the reporting period into those that are due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(F) The total duration in hours of CMS downtime for each CMS during the reporting period, and the total duration of CMS downtime as a percent of the total operating time of the affected source during that reporting period.

* * * * *

(I) The monitoring equipment manufacturer(s) and model number(s) and the pollutant or parameter monitored.

* * * * *

(M) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (e)(5)(iii)(C) of this section no longer applies. Instead, report the number of deviation to meet an applicable standard. For each instance, report the start date, start time and duration in hours of each deviation. For each deviation, the report must include a list of the affected sources or equipment, an estimate of the quantity in pounds of each regulated pollutant emitted over any emission limit, a description of the method used to estimate the emissions, and the cause of the deviation (including unknown cause, if applicable), as applicable, and the corrective action taken.

(N) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (e)(5)(iii)(E) of this section no longer applies. Instead, report a breakdown of the total duration in hours of the deviations during the reporting period into those that are due control equipment problems, process problems, other known causes, and other unknown causes.

* * * * *

(7) Include each new operating scenario which has been operated since the time period covered by the last compliance report and has not been submitted in the notification of compliance status report or a previous compliance report. For each new operating scenario, you must report the information specified in § 63.2525(b) and provide verification that the operating conditions for any associated control or treatment device have not been exceeded and that any required calculations and engineering analyses have been performed. For the purposes of this paragraph (e)(7), a revised operating scenario for an existing process is considered to be a new operating scenario.

(8) For process units added to a PUG, you must report the description and rationale specified in § 63.2525(i)(4). You must report your primary product redeterminations specified in § 63.2525(i)(5).

(9) Except as specified in §§ 63.2450(e)(4), 63.2480(f), and 63.2485(p) and (q) and paragraph (t) of this section, applicable records and information for periodic reports as specified in referenced subparts F, G, H, SS, UU, WW, and GGG of this part and subpart F of 40 CFR part 65.

(10) Except as specified in paragraph (e)(10)(ii) of this section, whenever you make a process change, or change any of the information submitted in the notification of compliance status report or a previous compliance report, that is not within the scope of an existing operating scenario, you must document the change in your compliance report. A process change does not include moving within a range of conditions identified in the standard batch, and a nonstandard batch does not constitute a process change.

(i) The notification must include all of the information in paragraphs (e)(10)(i)(A) through (C) of this section.

(A) A description of the process change.

(B) Revisions to any of the information reported in the original notification of compliance status report under paragraph (d) of this section.

(C) Information required by the notification of compliance status report under paragraph (d) of this section for changes involving the addition of processes or equipment at the affected source.

(ii) You must submit a report 60 days before the scheduled implementation date of any of the changes identified in paragraph (e)(10)(ii)(A), (B), or (C) of this section.

(A) Any change to the information contained in the precompliance report.

(B) A change in the status of a control device from small to large.

(C) A change from Group 2 to Group 1 for any emission point except for batch process vents that meet the conditions specified in § 63.2460(b)(6)(i).

(11) For each flare subject to the requirements in § 63.2450(e)(5), the compliance report must include the items specified in paragraphs (e)(11)(i) through (vi) of this section in lieu of the

information required in § 63.999(c)(3) of subpart SS.

(i) Records as specified in § 63.2525(m)(1) for each 15-minute block during which there was at least one minute when regulated material is routed to a flare and no pilot flame or flare flame is present. Include the start and stop time and date of each 15-minute block.

(ii) Visible emission records as specified in § 63.2525(m)(2)(iv) for each period of 2 consecutive hours during which visible emissions exceeded a total of 5 minutes.

(iii) The periods specified in § 63.2525(m)(6). Indicate the date and start and end times for each period, and the net heating value operating parameter(s) determined following the methods in § 63.670(k) through (n) of subpart CC as applicable.

(iv) For flaring events meeting the criteria in §§ 63.670(o)(3) of subpart CC and 63.2450(e)(5)(v):

(A) The start and stop time and date of the flaring event.

(B) The length of time in minutes for which emissions were visible from the flare during the event.

(C) For steam-assisted, air-assisted, and non-assisted flares, the start date, start time, and duration in minutes for periods of time that the flare tip velocity exceeds the maximum flare tip velocity determined using the methods in § 63.670(d)(2) of subpart CC and the maximum 15-minute block average flare tip velocity in ft/sec recorded during the event.

(D) Results of the root cause and corrective actions analysis completed during the reporting period, including the corrective actions implemented during the reporting period and, if applicable, the implementation schedule for planned corrective actions to be implemented subsequent to the reporting period.

(v) For pressure-assisted multi-point flares, the periods of time when the pressure monitor(s) on the main flare header show the burners operating outside the range of the manufacturer's specifications. Indicate the date and start and end times for each period.

(vi) For pressure-assisted multi-point flares, the periods of time when the staging valve position indicator monitoring system indicates a stage should not be in operation and is or when a stage should be in operation and is not. Indicate the date and start and end times for each period.

(12) For bypass lines subject to the requirements § 63.2450(e)(6), the compliance report must include the start date, start time, duration in hours, estimate of the volume of gas in standard cubic feet, the concentration of organic HAP in the gas in parts per million by volume and the resulting mass emissions of organic HAP in pounds that bypass a control device. For periods when the flow indicator is not operating, report the start date, start time, and duration in hours.

(13) For each nonregenerative adsorber and regenerative adsorber that is regenerated offsite subject to the requirements in § 63.2450(e)(7), you must report the date of each instance when breakthrough, as defined in § 63.2550(i), is detected between the first and second adsorber and the adsorber is not replaced according to § 63.2450(e)(7)(iii)(A).

(14) For any maintenance vent release exceeding the applicable limits in § 63.2450(v)(1), the compliance report must include the information specified in paragraphs (e)(14)(i) through (iv) of this section. For the purposes of this reporting requirement, if you comply with § 63.2450(v)(1)(iv) then you must report each venting event conducted under those provisions and include an explanation for each event as to why utilization of this alternative was required.

(i) Identification of the maintenance vent and the equipment served by the maintenance vent.

(ii) The date and time the maintenance vent was opened to the atmosphere.

(iii) The lower explosive limit in percent, vessel pressure in psig, or mass in pounds of VOC in the equipment, as applicable, at the start of atmospheric venting. If the 5 psig vessel pressure option in § 63.2450(v)(1)(ii) was used and active purging was initiated while the lower explosive limit was 10 percent or greater, also include the lower explosive limit of the vapors at the time active purging was initiated.

(iv) An estimate of the mass in pounds of organic HAP released during the entire atmospheric venting event.

(15) Compliance reports for pressure relief devices subject to the requirements § 63.2480(e) must include the information specified in paragraphs (e)(15)(i) through (iii) of this section.

(i) For pressure relief devices in organic HAP gas or vapor service, pursuant to § 63.2480(e)(1), report the instrument readings and dates for all readings of 500 ppmv or greater.

(ii) For pressure relief devices in organic HAP gas or vapor service subject to § 63.2480(e)(2), report the instrument readings and dates of instrument monitoring conducted.

(iii) For pressure relief devices in organic HAP service subject to § 63.2480(e)(3), report each pressure release to the atmosphere, including the start date, start time, and duration in minutes of the pressure release and an estimate of the mass quantity in pounds of each organic HAP released; the results of any root cause analysis and corrective action analysis completed during the reporting period, including the corrective actions implemented during the reporting period; and, if applicable, the implementation schedule for planned corrective actions to be implemented subsequent to the reporting period.

(16) For each heat exchange system subject to § 63.2490(d), beginning no later than the compliance dates specified in § 63.2445(g), the reporting requirements of § 63.104(f)(2) no longer apply; instead, the compliance report must include the information specified in paragraphs (e)(16)(i) through (v) of this section.

(i) The number of heat exchange systems at the plant site subject to the monitoring requirements in § 63.2490(d) during the reporting period;

(ii) The number of heat exchange systems subject to the monitoring requirements in § 63.2490(d) at the plant site found to be leaking during the reporting period;

(iii) For each monitoring location where the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate was determined to be equal to or greater than the applicable leak definitions specified in § 63.2490(d)(1)(v) during the reporting period, identification of the monitoring location (*e.g.,* unique monitoring location or heat exchange system ID number), the measured total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate, the date the leak was first identified, and, if applicable, the date the source of the leak was identified;

(iv) For leaks that were repaired during the reporting period (including delayed repairs), identification of the monitoring location associated with the repaired leak, the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate measured during re-monitoring to verify repair, and the re-monitoring date (*i.e.,* the effective date of repair); and

(v) For each delayed repair, identification of the monitoring location associated with the leak for which repair is delayed, the date when the delay of repair began, the date the repair is expected to be completed (if the leak is not repaired during the reporting period), the total strippable hydrocarbon concentration or total hydrocarbon mass emissions rate and date of each monitoring event conducted on the

delayed repair during the reporting period, and an estimate in pounds of the potential total hydrocarbon emissions over the reporting period associated with the delayed repair.

(17) For process vents and storage tanks in ethylene oxide service subject to the requirements of § 63.2493, the compliance report must include:

(i) The periods specified in § 63.2525(s)(4). Indicate the date and start and end times for each period.

(ii) If you obtain an instrument reading greater than 500 ppmv of a leak when monitoring a pressure vessel in accordance with § 63.2493(c)(2), submit a copy of the records specified in § 63.2525(s)(5)(ii).

(iii) Reports for equipment subject to the requirements of § 63.2493 as specified in paragraph (e)(9) of this section.

(f) *Performance test reports.* Beginning no later than October 13, 2020, you must submit performance test reports in accordance with this paragraph (f). Unless otherwise specified in this subpart, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed to be CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, CORE CBI Office, U.S. EPA Mailroom (C404–02), Attention: Group Leader, Measurement Policy Group, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraph (f)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c) emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(g) *CEMS relative accuracy test audit (RATA) Performance evaluation reports.* Beginning no later than October 13, 2020, you must start submitting CEMS RATA performance evaluation reports in accordance with this paragraph (g). Unless otherwise specified in this subpart, within 60 days after the date of completing each continuous monitoring system performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) *Performance evaluations of CMS measuring RATA pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Performance evaluations of CMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed to be CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, CORE CBI Office, U.S. EPA Mailroom (C404–02), Attention: Group Leader, Measurement Policy Group, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (g)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c) emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(h) *Claims of EPA system outage.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with that reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first

knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met that reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(i) *Claims of force majeure.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of *force majeure* for failure to timely comply with that reporting requirement. To assert a claim of *force majeure,* you must meet the requirements outlined in paragraphs (i)(1) through (5) of this section.

(1) You may submit a claim if a *force majeure* event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this paragraph (i)(1), a *force majeure* event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the *force majeure* event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the *force majeure* event;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of *force majeure* and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the *force majeure* event occurs.

■ 21. Section 63.2525 is amended by revising the introductory text and paragraphs (a), (e)(1)(ii), (f), (h), and (j) and adding paragraphs (l) through (u) to read as follows:

§ 63.2525 What records must I keep?

You must keep the records specified in paragraphs (a) through (t) of this section.

(a) Except as specified in §§ 63.2450(e)(4), 63.2480(f), and 63.2485(p) and (q) and paragraph (t) of this section, each applicable record required by subpart A of this part and in referenced subparts F, G, SS, UU, WW, and GGG of this part and in referenced subpart F of 40 CFR part 65.

* * * * *

(e) * * *

(1) * * *

(ii) You control the Group 2 batch process vents using a flare that meets the requirements of § 63.987 or § 63.2450(e)(5), as applicable.

* * * * *

(f) A record of each time a safety device is opened to avoid unsafe conditions in accordance with § 63.2450(p).

* * * * *

(h) Except as specified in paragraph (l) of this section, for each CEMS, you must keep records of the date and time that each deviation started and stopped, and whether the deviation occurred during a period of startup, shutdown, or malfunction or during another period.

* * * * *

(j) In the SSMP required by § 63.6(e)(3) of subpart A, you are not required to include Group 2 emission points, unless those emission points are used in an emissions average. For equipment leaks, the SSMP requirement is limited to control devices and is optional for other equipment. On and after August 12, 2023, this paragraph (j) no longer applies.

* * * * *

(l) Beginning no later than the compliance dates specified in § 63.2445(g), paragraph (h) of this section no longer applies. Instead, for each deviation from an emission limit, operating limit, or work practice standard, you must keep a record of the information specified in paragraph (l)(1) through (3) of this section. The records shall be maintained as specified in § 63.10(b)(1) of subpart A.

(1) In the event that an affected unit does not meet an applicable standard, record the number of deviations. For each deviation record the date, time, and duration of each deviation.

(2) For each deviation from an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(3) Record actions taken to minimize emissions in accordance with § 63.2450(u) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(m) For each flare subject to the requirements in § 63.2450(e)(5), you must keep records specified in paragraphs (m)(1) through (14) of this section in lieu of the information required in § 63.998(a)(1) of subpart SS.

(1) Retain records of the output of the monitoring device used to detect the presence of a pilot flame or flare flame as required in § 63.670(b) of subpart CC and the presence of a pilot flame as required in § 63.2450(e)(5)(viii)(D) for a minimum of 2 years. Retain records of each 15-minute block during which there was at least one minute that no pilot flame or flare flame is present when regulated material is routed to a flare for a minimum of 5 years. For a pressure-assisted multi-point flare that uses cross-lighting, retain records of each 15-minute block during which there was at least one minute that no pilot flame is present on each stage when regulated material is routed to a flare for a minimum of 5 years. You may reduce the collected minute-by-minute data to a 15-minute block basis with an indication of whether there was at least one minute where no pilot flame or flare flame was present.

(2) Retain records of daily visible emissions observations as specified in paragraphs (m)(2)(i) through (iv) of this section, as applicable, for a minimum of 3 years.

(i) To determine when visible emissions observations are required, the record must identify all periods when regulated material is vented to the flare.

(ii) If visible emissions observations are performed using Method 22 of 40

CFR part 60, appendix A–7, then the record must identify whether the visible emissions observation was performed, the results of each observation, total duration of observed visible emissions, and whether it was a 5-minute or 2-hour observation. Record the date and start time of each visible emissions observation.

(iii) If a video surveillance camera is used pursuant to § 63.670(h)(2) of subpart CC, then the record must include all video surveillance images recorded, with time and date stamps.

(iv) For each 2 hour period for which visible emissions are observed for more than 5 minutes in 2 consecutive hours, then the record must include the date and start and end time of the 2 hour period and an estimate of the cumulative number of minutes in the 2 hour period for which emissions were visible.

(3) The 15-minute block average cumulative flows for flare vent gas and, if applicable, total steam, perimeter assist air, and premix assist air specified to be monitored under § 63.670(i) of subpart CC, along with the date and time interval for the 15-minute block. If multiple monitoring locations are used to determine cumulative vent gas flow, total steam, perimeter assist air, and premix assist air, then retain records of the 15-minute block average flows for each monitoring location for a minimum of 2 years, and retain the 15-minute block average cumulative flows that are used in subsequent calculations for a minimum of 5 years. If pressure and temperature monitoring is used, then retain records of the 15-minute block average temperature, pressure, and molecular weight of the flare vent gas or assist gas stream for each measurement location used to determine the 15-minute block average cumulative flows for a minimum of 2 years, and retain the 15-minute block average cumulative flows that are used in subsequent calculations for a minimum of 5 years.

(4) The flare vent gas compositions specified to be monitored under § 63.670(j) of subpart CC. Retain records of individual component concentrations from each compositional analysis for a minimum of 2 years. If an NHVvg analyzer is used, retain records of the 15-minute block average values for a minimum of 5 years.

(5) Each 15-minute block average operating parameter calculated following the methods specified in § 63.670(k) through (n) of subpart CC, as applicable.

(6) All periods during which operating values are outside of the applicable operating limits specified in §§ 63.670(d) through (f) of subpart CC and 63.2450(e)(5)(viii) when regulated material is being routed to the flare.

(7) All periods during which you do not perform flare monitoring according to the procedures in § 63.670(g) through (j) of subpart CC.

(8) For pressure-assisted multi-point flares, if a stage of burners on the flare uses cross-lighting, then a record of any changes made to the distance between burners.

(9) For pressure-assisted multi-point flares, all periods when the pressure monitor(s) on the main flare header show burners are operating outside the range of the manufacturer's specifications. Indicate the date and time for each period, the pressure measurement, the stage(s) and number of burners affected, and the range of manufacturer's specifications.

(10) For pressure-assisted multi-point flares, all periods when the staging valve position indicator monitoring system indicates a stage of the pressure-assisted multi-point flare should not be in operation and when a stage of the pressure-assisted multi-point flare should be in operation and is not. Indicate the date and time for each period, whether the stage was supposed to be open, but was closed or vice versa, and the stage(s) and number of burners affected.

(11) Records of periods when there is flow of vent gas to the flare, but when there is no flow of regulated material to the flare, including the start and stop time and dates of periods of no regulated material flow.

(12) Records when the flow of vent gas exceeds the smokeless capacity of the flare, including start and stop time and dates of the flaring event.

(13) Records of the root cause analysis and corrective action analysis conducted as required in §§ 63.670(o)(3) of subpart CC and 63.2450(e)(5)(v), including an identification of the affected flare, the date and duration of the event, a statement noting whether the event resulted from the same root cause(s) identified in a previous analysis and either a description of the recommended corrective action(s) or an explanation of why corrective action is not necessary under § 63.670(o)(5)(i) of subpart CC.

(14) For any corrective action analysis for which implementation of corrective actions are required in § 63.670(o)(5) of subpart CC, a description of the corrective action(s) completed within the first 45 days following the discharge and, for action(s) not already completed, a schedule for implementation, including proposed commencement and completion dates.

(n) For each flow event from a bypass line subject to the requirements in § 63.2450(e)(6), you must maintain records sufficient to determine whether or not the detected flow included flow requiring control. For each flow event from a bypass line requiring control that is released either directly to the atmosphere or to a control device not meeting the requirements specified in Tables 1 through 7 to this subpart, you must include an estimate of the volume of gas, the concentration of organic HAP in the gas and the resulting emissions of organic HAP that bypassed the control device using process knowledge and engineering estimates.

(o) For each nonregenerative adsorber and regenerative adsorber that is regenerated offsite subject to the requirements in § 63.2450(e)(7), you must keep the applicable records specified in paragraphs (o)(1) through (4) of this section.

(1) Outlet HAP or TOC concentration for each adsorber bed measured during each performance test conducted.

(2) Daily outlet HAP or TOC concentration.

(3) Date and time you last replaced the adsorbent.

(4) If you conduct monitoring less frequently than daily as specified in § 63.2450(e)(7)(iii)(B), you must record the average life of the bed.

(p) For each maintenance vent opening subject to the requirements in § 63.2450(v), you must keep the applicable records specified in paragraphs (p)(1) through (5) of this section.

(1) You must maintain standard site procedures used to deinventory equipment for safety purposes (*e.g.,* hot work or vessel entry procedures) to document the procedures used to meet the requirements in § 63.2450(v). The current copy of the procedures must be retained and available on-site at all times. Previous versions of the standard site procedures, as applicable, must be retained for five years.

(2) If complying with the requirements of § 63.2450(v)(1)(i) and the lower explosive limit at the time of the vessel opening exceeds 10 percent, identification of the maintenance vent, the process units or equipment associated with the maintenance vent, the date of maintenance vent opening, and the lower explosive limit at the time of the vessel opening.

(3) If complying with the requirements of § 63.2450(v)(1)(ii) and either the vessel pressure at the time of the vessel opening exceeds 5 psig or the lower explosive limit at the time of the active purging was initiated exceeds 10 percent, identification of the

maintenance vent, the process units or equipment associated with the maintenance vent, the date of maintenance vent opening, the pressure of the vessel or equipment at the time of discharge to the atmosphere and, if applicable, the lower explosive limit of the vapors in the equipment when active purging was initiated.

(4) If complying with the requirements of § 63.2450(v)(1)(iii), records of the estimating procedures used to determine the total quantity of VOC in the equipment and the type and size limits of equipment that contain less than 50 pounds of VOC at the time of maintenance vent opening. For each maintenance vent opening that contains greater than 50 pounds of VOC for which the deinventory procedures specified in paragraph (p)(1) of this section are not followed or for which the equipment opened exceeds the type and size limits established in the records specified in this paragraph (p)(4), records that identify the maintenance vent, the process units or equipment associated with the maintenance vent, the date of maintenance vent opening, and records used to estimate the total quantity of VOC in the equipment at the time the maintenance vent was opened to the atmosphere.

(5) If complying with the requirements of § 63.2450(v)(1)(iv), identification of the maintenance vent, the process units or equipment associated with the maintenance vent, records documenting actions taken to comply with other applicable alternatives and why utilization of this alternative was required, the date of maintenance vent opening, the equipment pressure and lower explosive limit of the vapors in the equipment at the time of discharge, an indication of whether active purging was performed and the pressure of the equipment during the installation or removal of the blind if active purging was used, the duration the maintenance vent was open during the blind installation or removal process, and records used to estimate the total quantity of VOC in the equipment at the time the maintenance vent was opened to the atmosphere for each applicable maintenance vent opening.

(q) For each pressure relief device subject to the pressure release management work practice standards in § 63.2480(e), you must keep the records specified in paragraphs (q)(1) through (3) of this section.

(1) Records of the prevention measures implemented as required in § 63.2480(e)(3)(ii).

(2) Records of the number of releases during each calendar year and the number of those releases for which the root cause was determined to be a *force majeure* event. Keep these records for the current calendar year and the past 5 calendar years.

(3) For each release to the atmosphere, you must keep the records specified in paragraphs (q)(3)(i) through (iv) of this section.

(i) The start and end time and date of each pressure release to the atmosphere.

(ii) Records of any data, assumptions, and calculations used to estimate of the mass quantity of each organic HAP released during the event.

(iii) Records of the root cause analysis and corrective action analysis conducted as required in § 63.2480(e)(3)(iii), including an identification of the affected facility, a statement noting whether the event resulted from the same root cause(s) identified in a previous analysis and either a description of the recommended corrective action(s) or an explanation of why corrective action is not necessary under § 63.2480(e)(7)(i).

(iv) For any corrective action analysis for which implementation of corrective actions are required in § 63.2480(e)(7), a description of the corrective action(s) completed within the first 45 days following the discharge and, for action(s) not already completed, a schedule for implementation, including proposed commencement and completion dates.

(r) For each heat exchange system, beginning no later than the compliance dates specified in § 63.2445(g), the recordkeeping requirements of § 63.104(f)(1) no longer apply; instead, you must keep records in paragraphs (r)(1) through (4) of this section.

(1) Monitoring data required by § 63.2490(d) that indicate a leak, the date the leak was detected, or, if applicable, the basis for determining there is no leak.

(2) The dates of efforts to repair leaks.

(3) The method or procedures used to confirm repair of a leak and the date the repair was confirmed.

(4) Documentation of delay of repair as specified in paragraphs (r)(4)(i) through (iv) of this section.

(i) The reason(s) for delaying repair.

(ii) A schedule for completing the repair as soon as practical.

(iii) The date and concentration or mass emissions rate of the leak as first identified and the results of all subsequent monitoring events during the delay of repair.

(iv) An estimate of the potential total hydrocarbon emissions from the leaking heat exchange system or heat exchanger for each required delay of repair monitoring interval following the procedures in paragraphs (r)(4)(iv)(A) through (C) of this section.

(A) If you comply with the total strippable hydrocarbon concentration leak action level, as specified in § 63.2490(d)(1)(iv), you must calculate the mass emissions rate by complying with the requirements of § 63.2490(d)(1)(iii)(B) or by determining the mass flow rate of the cooling water at the monitoring location where the leak was detected. If the monitoring location is an individual cooling tower riser, determine the total cooling water mass flow rate to the cooling tower. Cooling water mass flow rates may be determined using direct measurement, pump curves, heat balance calculations, or other engineering methods. If you determine the mass flow rate of the cooling water, calculate the mass emissions rate by converting the stripping gas leak concentration (in ppmv as methane) to an equivalent liquid concentration, in parts per million by weight (ppmw), using equation 7–1 from ''Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources'' (incorporated by reference—see § 63.14) and multiply the equivalent liquid concentration by the mass flow rate of the cooling water.

(B) For delay of repair monitoring intervals prior to repair of the leak, calculate the potential total hydrocarbon emissions for the leaking heat exchange system or heat exchanger for the monitoring interval by multiplying the mass emissions rate, determined in § 63.2490(d)(1)(iii)(B) or paragraph (r)(4)(iv)(A) of this section, by the duration of the delay of repair monitoring interval. The duration of the delay of repair monitoring interval is the time period starting at midnight on the day of the previous monitoring event or at midnight on the day the repair would have had to be completed if the repair had not been delayed, whichever is later, and ending at midnight of the day the of the current monitoring event.

(C) For delay of repair monitoring intervals ending with a repaired leak, calculate the potential total hydrocarbon emissions for the leaking heat exchange system or heat exchanger for the final delay of repair monitoring interval by multiplying the duration of the final delay of repair monitoring interval by the mass emissions rate determined for the last monitoring event prior to the re-monitoring event used to verify the leak was repaired. The duration of the final delay of repair monitoring interval is the time period starting at midnight of the

day of the last monitoring event prior to re-monitoring to verify the leak was repaired and ending at the time of the re-monitoring event that verified that the leak was repaired.

(s) For process vents and storage tanks in ethylene oxide service subject to the requirements of § 63.2493, you must keep the records specified in paragraphs (s)(1) through (5) of this section in addition to those records specified in paragraph (a) of this section. Records for equipment in ethylene oxide service subject to the requirements of § 63.2493 are specified in paragraph (a) of this section.

(1) For process vents, include all uncontrolled, undiluted ethylene oxide concentration measurements, and the calculations you used to determine the total uncontrolled ethylene oxide mass emission rate for the sum of all vent gas streams.

(2) For storage tanks, records of the concentration of ethylene oxide of the fluid stored in each storage tank.

(3) For equipment, records of the percent ethylene oxide content of the process fluid and the method used to determine it.

(4) If you vent emissions through a closed-vent system to a non-flare control device, then you must keep records of all periods during which operating values are outside of the applicable operating limits specified in § 63.2493(b)(4) through (6) when regulated material is being routed to the non-flare control device. The record must specify the operating parameter, the applicable limit, and the highest (for maximum operating limits) or lowest (for minimum operating limits) value recorded during the period.

(5) For pressure vessels subject to § 63.2493(c), records as specified in paragraphs (s)(5)(i) through (iv) of this section.

(i) The date of each performance test conducted according to § 63.2493(c)(2).

(ii) The instrument reading of each performance test conducted according to § 63.2493(c)(2), including the following:

(A) Date each defect was detected.

(B) Date of the next performance test that shows the instrument reading is less than 500 ppmv.

(C) Start and end dates of each period after the date in paragraph (s)(5)(ii)(A) of this section when the pressure vessel was completely empty.

(D) Estimated emissions from each defect.

(t) Any records required to be maintained by this part that are submitted electronically via the EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

(u) Beginning no later than the compliance dates specified in § 63.2445(g), the referenced provisions specified in paragraphs (u)(1) through (8) of this section do not apply when demonstrating compliance with paragraph (a) of this section.

(1) Section 63.103(c)(2)(i) of subpart F.

(2) Section 63.103(c)(2)(ii) of subpart F.

(3) The phrase ''start-up, shutdown and malfunction and'' from § 63.103(c)(3) of subpart F.

(4) The phrase ''other than startups, shutdowns, or malfunctions (*e.g.,* a temperature reading of −200 °C on a boiler),'' from § 63.152(g)(1)(i) of subpart G.

(5) The phrase ''other than a startup, shutdown, or malfunction'' from § 63.152(g)(1)(ii)(C) of subpart G.

(6) The phrase ''other than startups, shutdowns, or malfunctions'' from § 63.152(g)(1)(iii) of subpart G.

(7) The phrase ''other than a startup, shutdown, or malfunction'' from § 63.152(g)(2)(iii) of subpart G.

(8) Section 63.152(g)(2)(iv)(A) of subpart G.

■ 22. Section 63.2535 is amended by revising the introductory text and paragraphs (d) and (k) and adding paragraph (m) to read as follows:

§ 63.2535 What compliance options do I have if part of my plant is subject to both this subpart and another subpart?

For any equipment, emission stream, or wastewater stream not subject to § 63.2493 but subject to other provisions of both this subpart and another subpart, you may elect to comply only with the provisions as specified in paragraphs (a) through (l) of this section. You also must identify the subject equipment, emission stream, or wastewater stream, and the provisions with which you will comply, in your notification of compliance status report required by § 63.2520(d).

* * * * *

(d) *Compliance with subpart I, GGG, or MMM of this part.* After the compliance dates specified in § 63.2445, if you have an affected source with equipment subject to subpart I, GGG, or MMM of this part, you may elect to comply with the provisions of subpart H, GGG, or MMM of this part, respectively, for all such equipment, except the affirmative defense requirements in subparts GGG and MMM no longer apply.

* * * * *

(k) *Compliance with 40 CFR part 60, subpart VV or VVa, and 40 CFR part 61, subpart V.* Except as specified in paragraphs (k)(1) and (2) of this section, after the compliance date specified in § 63.2445, if you have an affected source with equipment that is also subject to the requirements of 40 CFR part 60, subpart VV or VVa, or 40 CFR part 61, subpart V, you may elect to apply this subpart to all such equipment. After the compliance date specified in § 63.2445, if you have an affected source with equipment to which this subpart does not apply, but which is subject to the requirements of 40 CFR part 60, subpart VV or VVa, or 40 CFR part 61, subpart V, you may elect to apply this subpart to all such equipment. If you elect either of the methods of compliance in this paragraph (k), you must consider all total organic compounds, minus methane and ethane, in such equipment for purposes of compliance with this subpart, as if they were organic HAP. Compliance with the provisions of this subpart, in the manner described in this paragraph (k), will constitute compliance with 40 CFR part 60, subpart VV or VVa, and 40 CFR part 61, subpart V, as applicable.

(1) The provision in § 63.2480(b)(4) does not apply to connectors in gas/vapor and light liquid service that are subject to monitoring under 40 CFR 60.482–11a if complying with the compliance option in this paragraph (k).

(2) Beginning no later than the compliance dates specified in § 63.2445(g), equipment that must be controlled according to this subpart and subpart VVa of 40 CFR part 60 is required only to comply with the equipment leak requirements of this subpart, except you must also comply with the calibration drift assessment requirements specified at 40 CFR 60.485a(b)(2) if they are required to do so in subpart VVa of 40 CFR part 60. When complying with the calibration drift assessment requirements at 40 CFR 60.485a(b)(2), the requirement at 40 CFR 60.486a(e)(8)(v) to record the instrument reading for each scale used applies.

* * * * *

(m) *Overlap of this subpart with other regulations for flares.* (1) Beginning no later than the compliance dates specified in § 63.2445(g), flares that control ethylene oxide emissions from affected sources in ethylene oxide service as defined in § 63.2550 or are used to control emissions from MCPUs that produce olefins and polyolefins, subject to the provisions of 40 CFR

60.18 or 63.11, and used as a control device for an emission point subject to the emission limits and work practice standards in Tables 1, 2, 4 or 5 to this subpart are required to comply only with the provisions specified in § 63.2450(e)(5). At any time before the compliance dates specified in § 63.2445(g), flares that are subject to the provisions of 40 CFR 60.18 or 63.11 and elect to comply with the requirements in § 63.2450(e)(5) are required to comply only with the provisions specified in this subpart. For purposes of compliance with this paragraph (m), ''MCPUs that produces olefins or polyolefins'' includes only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product. By-products and impurities as defined in § 63.101, as well as wastes and trace contaminants, are not considered products.

(2) Beginning no later than the compliance dates specified in § 63.2445(g), flares subject to § 63.987 and used as a control device for an emission point subject to the emission limits and work practice standards in Tables 1, 2, 4 or 5 to this subpart are only required to comply with § 63.2450(e)(5).

(3) Beginning no later than the compliance dates specified in § 63.2445(g), flares subject to the requirements in subpart CC of this part and used as a control device for an emission point subject to the emission limits and work practice standards in Tables 1, 2, 4 or 5 to this subpart are only required to comply with the flare requirements in subpart CC of this part. This paragraph (m)(3) does not apply to multi-point pressure assisted flares.

■ 23. Section 63.2545 is amended by revising paragraph (b) introductory text and adding paragraph (b)(5) to read as follows:

§ 63.2545 Who implements and enforces this subpart?

* * * * *

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under subpart E of this part, the authorities contained in paragraphs (b)(1) through (5) of this section are retained by the Administrator of U.S. EPA and are not delegated to the state, local, or tribal agency.

* * * * *

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 24. Section 63.2550 is amended in paragraph (i) by:

■ a. Revising paragraphs (4) and (8) in the definition of ''Batch process vent'';
■ b. Adding, in alphabetical order, definitions for ''Bench-scale process'' and ''Breakthrough'';
■ c. Adding paragraphs (8), (9), (10), and (11) in the definition of ''Continuous process vent'';
■ d. Revising paragraph (3) in the definition of ''Deviation'';
■ e. Adding, in alphabetical order, definitions for ''Force majeure,'' ''Heat exchange system,'' ''In ethylene oxide service,'' and ''Loading rack'';
■ f. Revising paragraph (6) in the definition of ''Miscellaneous organic chemical manufacturing process''; and
■ g. Adding, in alphabetical order, definitions for ''Pressure release,'' ''Pressure relief device,'' ''Pressure vessel,'' ''Relief valve,'' and ''Thermal expansion relief valve.''

The revisions and additions read as follows:

§ 63.2550 What definitions apply to this subpart?

* * * * *

(i) * * *

Batch process vent * * *

(4) Gaseous streams routed to a fuel gas system(s) unless on and after August 12, 2023, the fuel gas system(s) supplies a flare of which 50 percent or more of the fuel gas burned in the flare is derived from an MCPU that has processes and/or equipment in ethylene oxide service, or produces olefins or polyolefins;

* * * * *

(8) Except for batch process vents in ethylene oxide service, emission streams from emission episodes that are undiluted and uncontrolled containing less than 50 ppmv HAP are not part of any batch process vent. A vent from a unit operation, or a vent from multiple unit operations that are manifolded together, from which total uncontrolled HAP emissions are less than 200 lb/yr is not a batch process vent; emissions for all emission episodes associated with the unit operation(s) must be included in the determination of the total mass emitted. The HAP concentration or mass emission rate may be determined using any of the following: Process knowledge that no HAP are present in the emission stream; an engineering assessment as discussed in § 63.1257(d)(2)(ii), except that you do not need to demonstrate that the equations in § 63.1257(d)(2)(i) do not apply, and the precompliance reporting requirements specified in § 63.1257(d)(2)(ii)(E) do not apply for the purposes of this demonstration; equations specified in § 63.1257(d)(2)(i), as applicable; test data using Method 18 of 40 CFR part 60, appendix A; or any other test method that has been validated according to the procedures in EPA Method 301 of appendix A to this part.

Bench-scale process means a process (other than a research and development facility) that is operated on a small scale, such as one capable of being located on a laboratory bench top. This bench-scale equipment will typically include reagent feed vessels, a small reactor and associated product separator, recovery and holding equipment. These processes are only capable of producing small quantities of product.

* * * * *

Breakthrough means the time when the level of HAP or TOC, measured at the outlet of the first bed, has been detected is at the highest concentration allowed to be discharged from the adsorber system and indicates that the adsorber bed should be replaced.

* * * * *

Continuous process vent * * *

(8) On and after August 12, 2023, § 63.107(h)(3) applies unless the fuel gas system supplies a flare of which 50 percent or more of the fuel gas burned in the flare is derived from an MCPU that has processes and/or equipment in ethylene oxide service, or produces olefins or polyolefins.

(9) On and after August 12, 2023, § 63.107(h)(9) no longer applies.

(10) On and after August 12, 2023, § 63.107(i) no longer applies. Instead, a process vent is the point of discharge to the atmosphere (or the point of entry into a control device, if any) of a gas stream if the gas stream meets the criteria specified in this paragraph. The gas stream would meet the characteristics specified in § 63.107(b) through (g) of subpart F, but, for purposes of avoiding applicability, has been deliberately interrupted, temporarily liquefied, routed through any item of equipment for no process purpose, or disposed of in a flare that does not meet the criteria in § 63.11(b) of subpart A or § 63.2450(e)(5) as applicable, or an incinerator that does not reduce emissions of organic HAP by 98 percent or to a concentration of 20 parts per million by volume, whichever is less stringent.

(11) Section 63.107(d) does not apply to continuous process vents in ethylene oxide service.

* * * * *

Deviation * * *

(3) Before August 12, 2023, fails to meet any emission limit, operating limit, or work practice standard in this subpart during startup, shutdown, or

malfunction, regardless of whether or not such failure is permitted by this subpart. On and after August 12, 2023, this paragraph (3) no longer applies.

* * * * *

Force majeure event means a release of HAP, either directly to the atmosphere from a pressure relief device or discharged via a flare, that is demonstrated to the satisfaction of the Administrator to result from an event beyond the owner or operator's control, such as natural disasters; acts of war or terrorism; loss of a utility external to the MCPU (*e.g.,* external power curtailment), excluding power curtailment due to an interruptible service agreement; and fire or explosion originating at a near or adjoining facility outside of the miscellaneous organic chemical manufacturing process unit that impacts the miscellaneous organic chemical manufacturing process unit's ability to operate.

* * * * *

Heat exchange system means a device or collection of devices used to transfer heat from process fluids to water without intentional direct contact of the process fluid with the water (*i.e.,* non-contact heat exchanger) and to transport and/or cool the water in a closed-loop recirculation system (cooling tower system) or a once-through system (*e.g.,* river or pond water). For closed-loop recirculation systems, the heat exchange system consists of a cooling tower, all miscellaneous organic chemical manufacturing process unit heat exchangers that are in organic HAP service, as defined in this subpart, serviced by that cooling tower, and all water lines to and from these miscellaneous organic chemical manufacturing process unit heat exchangers. For once-through systems, the heat exchange system consists of all heat exchangers that are in organic HAP service, as defined in this subpart, servicing an individual miscellaneous organic chemical manufacturing process unit and all water lines to and from these heat exchangers. Sample coolers or pump seal coolers are not considered heat exchangers for the purpose of this definition and are not part of the heat exchange system. Intentional direct contact with process fluids results in the formation of a wastewater.

* * * * *

In ethylene oxide service means the following:

(1) For equipment leaks, any equipment that contains or contacts a fluid (liquid or gas) that is at least 0.1 percent by weight of ethylene oxide. If information exists that suggests ethylene oxide could be present in equipment, the equipment is considered to be ''in ethylene oxide service'' unless sampling and analysis is performed as specified in § 63.2492 to demonstrate that the equipment does not meet the definition of being ''in ethylene oxide service''. Examples of information that could suggest ethylene oxide could be present in equipment, include calculations based on safety data sheets, material balances, process stoichiometry, or previous test results provided the results are still relevant to the current operating conditions.

(2) For process vents, each batch and continuous process vent in a process that, when uncontrolled, contains a concentration of greater than or equal to 1 ppmv undiluted ethylene oxide, and when combined, the sum of all these process vents would emit uncontrolled ethylene oxide emissions greater than or equal to 5 lb/yr (2.27 kg/yr). If information exists that suggests ethylene oxide could be present in a batch or continuous process vent, then the batch or continuous process vent is considered to be ''in ethylene oxide service'' unless an analysis is performed as specified in § 63.2492 to demonstrate that the batch or continuous process vent does not meet the definition of being ''in ethylene oxide service''. Examples of information that could suggest ethylene oxide could be present in a batch or continuous process vent, include calculations based on safety data sheets, material balances, process stoichiometry, or previous test results provided the results are still relevant to the current operating conditions.

(3) For storage tanks, storage tanks of any capacity and vapor pressure storing a liquid that is at least 0.1 percent by weight of ethylene oxide. If knowledge exists that suggests ethylene oxide could be present in a storage tank, then the storage tank is considered to be ''in ethylene oxide service'' unless sampling and analysis is performed as specified in § 63.2492 to demonstrate that the storage tank does not meet the definition of being ''in ethylene oxide service''. The exemptions for ''vessels storing organic liquids that contain HAP only as impurities'' and ''pressure vessels designed to operate in excess of 204.9 kilopascals and without emissions to the atmosphere'' listed in the definition of ''storage tank'' in this section do not apply for storage tanks that may be in ethylene oxide service. Examples of information that could suggest ethylene oxide could be present in a storage tank, include calculations based on safety data sheets, material balances, process stoichiometry, or previous test results provided the results are still relevant to the current operating conditions.

* * * * *

Loading rack means a single system used to fill tank trucks and railcars at a single geographic site. Loading equipment and operations that are physically separate (*i.e.,* do not share common piping, valves, and other equipment) are considered to be separate loading racks.

* * * * *

Miscellaneous organic chemical manufacturing process * * *

(6) The end of a process that produces a solid material is either up to and including the dryer or extruder, or for a polymer production process without a dryer or extruder, it is up to and including the die plate or solid-state reactor, except in two cases. If the dryer, extruder, die plate, or solid-state reactor is followed by an operation that is designed and operated to remove HAP solvent or residual HAP monomer from the solid, then the solvent removal operation is the last step in the process. If the dried solid is diluted or mixed with a HAP-based solvent, then the solvent removal operation is the last step in the process.

* * * * *

Pressure release means the emission of materials resulting from the system pressure being greater than the set pressure of the pressure relief device. This release can be one release or a series of releases over a short time period.

Pressure relief device means a valve, rupture disk, or similar device used only to release an unplanned, nonroutine discharge of gas from process equipment in order to avoid safety hazards or equipment damage. A pressure relief device discharge can result from an operator error, a malfunction such as a power failure or equipment failure, or other unexpected cause. Such devices include conventional, spring-actuated relief valves, balanced bellows relief valves, pilot-operated relief valves, rupture disks, and breaking, buckling, or shearing pin devices. Devices that are actuated either by a pressure of less than or equal to 2.5 pounds per square inch gauge or by a vacuum are not pressure relief devices.

Pressure vessel means a storage vessel that is used to store liquids or gases and is designed not to vent to the atmosphere as a result of compression of the vapor headspace in the pressure vessel during filling of the pressure vessel to its design capacity.

* * * * *

Relief valve means a type of pressure relief device that is designed to re-close after the pressure relief.

* * * * *

Thermal expansion relief valve means a pressure relief valve designed to protect equipment from excess pressure due to thermal expansion of blocked liquid-filled equipment or piping due to ambient heating or heat from a heat tracing system. Pressure relief valves designed to protect equipment from excess pressure due to blockage against a pump or compressor or due to fire contingency are not thermal expansion relief valves.

* * * * *

■ 25. Table 1 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2455, you must meet each emission limit and work practice standard in the following table that applies to your continuous process vents:

TABLE 1 TO SUBPART FFFF OF PART 63—EMISSION LIMITS AND WORK PRACTICE STANDARDS FOR CONTINUOUS PROCESS VENTS

For each . . .	For which . . .	Then you must . . .
1. Group 1 continuous process vent	a. Not applicable	i. Reduce emissions of total organic HAP by ≥98 percent by weight or to an outlet process concentration ≤20 ppmv as organic HAP or TOC by venting emissions through a closed-vent system to any combination of control devices (except a flare); or ii. Reduce emissions of total organic HAP by venting emissions through a closed vent system to a flare; or iii. Use a recovery device to maintain the TRE above 1.9 for an existing source or above 5.0 for a new source.
2. Halogenated Group 1 continuous process vent stream.	a. You use a combustion control device to control organic HAP emissions.	i. Use a halogen reduction device after the combustion device to reduce emissions of hydrogen halide and halogen HAP by ≥99 percent by weight, or to ≤0.45 kg/hr, or to ≤20 ppmv; or ii. Use a halogen reduction device before the combustion device to reduce the halogen atom mass emission rate to ≤0.45 kg/hr or to a concentration ≤20 ppmv.
3. Group 2 continuous process vent at an existing source.	You use a recovery device to maintain the TRE level >1.9 but ≤5.0.	Comply with the requirements in § 63.2450(e)(4) and the requirements in § 63.993 and the requirements referenced therein.
4. Group 2 continuous process vent at a new source.	You use a recovery device to maintain the TRE level >5.0 but ≤8.0.	Comply with the requirements in § 63.2450(e)(4) and the requirements in § 63.993 and the requirements referenced therein.
5. Continuous process vent	Beginning no later than the compliance dates specified in § 63.2445(i), the continuous process vent contains ethylene oxide such that it is considered to be in ethylene oxide service as defined in § 63.2550.	Comply with the applicable emission limits specified in items 1 through 4 of this Table, and also: i. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a flare; or ii. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a control device that reduces ethylene oxide by ≥99.9 percent by weight, or to a concentration <1 ppmv for each process vent or to <5 pounds per year for all combined process vents.

■ 26. Table 2 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2460, you must meet each emission limit and work practice standard in the following table that applies to your batch process vents:

TABLE 2 TO SUBPART FFFF OF PART 63—EMISSION LIMITS AND WORK PRACTICE STANDARDS FOR BATCH PROCESS VENTS

For each . . .	Then you must . . .	And you must . . .
1. Process with Group 1 batch process vents.	a. Reduce collective uncontrolled organic HAP emissions from the sum of all batch process vents within the process by ≥98 percent by weight by venting emissions from a sufficient number of the vents through one or more closed-vent systems to any combination of control devices (except a flare); or	Not applicable.
	b. Reduce collective uncontrolled organic HAP emissions from the sum of all batch process vents within the process by ≥95 percent by weight by venting emissions from a sufficient number of the vents through one or more closed-vent systems to any combination of recovery devices or a biofilter, except you may elect to comply with the requirements of subpart WW of this part for any process tank; or	Not applicable.

TABLE 2 TO SUBPART FFFF OF PART 63—EMISSION LIMITS AND WORK PRACTICE STANDARDS FOR BATCH PROCESS VENTS—Continued

For each . . .	Then you must . . .	And you must . . .
	c. Reduce uncontrolled organic HAP emissions from one or more batch process vents within the process by venting through a closed-vent system to a flare or by venting through one or more closed-vent systems to any combination of control devices (excluding a flare) that reduce organic HAP to an outlet concentration ≤20 ppmv as TOC or total organic HAP.	For all other batch process vents within the process, reduce collective organic HAP emissions as specified in item 1.a and/or item 1.b of this Table.
2. Halogenated Group 1 batch process vent for which you use a combustion device to control organic HAP emissions.	a. Use a halogen reduction device after the combustion control device; or	i. Reduce overall emissions of hydrogen halide and halogen HAP by ≥99 percent; or ii. Reduce overall emissions of hydrogen halide and halogen HAP to ≤0.45 kg/hr; or iii. Reduce overall emissions of hydrogen halide and halogen HAP to a concentration ≤20 ppmv.
	b. Use a halogen reduction device before the combustion control device.	Reduce the halogen atom mass emission rate to ≤0.45 kg/hr or to a concentration ≤20 ppmv.
3. Batch process vent that contains ethylene oxide such that it is considered to be in ethylene oxide service as defined in § 63.2550.	Beginning no later than the compliance dates specified in § 63.2445(i), comply with the applicable emission limits specified in items 1 and 2 of this Table, and also: i. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a flare; or ii. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a control device that reduces ethylene oxide by ≥99.9 percent by weight, or to a concentration <1 ppmv for each process vent or to <5 pounds per year for all combined process vents.	Not applicable.

■ 27. Table 4 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2470, you must meet each emission limit in the following table that applies to your storage tanks:

TABLE 4 TO SUBPART FFFF OF PART 63—EMISSION LIMITS FOR STORAGE TANKS

For each . . .	For which . . .	Then you must . . .
1. Group 1 storage tank	a. The maximum true vapor pressure of total HAP at the storage temperature is ≥76.6 kilopascals.	i. Reduce total HAP emissions by ≥95 percent by weight or to ≤20 ppmv of TOC or organic HAP and ≤20 ppmv of hydrogen halide and halogen HAP by venting emissions through a closed vent system to any combination of control devices (excluding a flare); or ii. Reduce total organic HAP emissions by venting emissions through a closed vent system to a flare; or iii. Comply with the requirements in § 63.2450(e)(4), as applicable; and reduce total HAP emissions by venting emissions to a fuel gas system or process in accordance with § 63.982(d) and the requirements referenced therein.[1]
	b. The maximum true vapor pressure of total HAP at the storage temperature is <76.6 kilopascals.	i. Comply with the requirements of subpart WW of this part, except as specified in § 63.2470; or ii. Reduce total HAP emissions by ≥95 percent by weight or to ≤20 ppmv of TOC or organic HAP and ≤20 ppmv of hydrogen halide and halogen HAP by venting emissions through a closed vent system to any combination of control devices (excluding a flare); or iii. Reduce total organic HAP emissions by venting emissions through a closed vent system to a flare; or iv. Comply with the requirements in § 63.2450(e)(4), as applicable; and reduce total HAP emissions by venting emissions to a fuel gas system or process in accordance with § 63.982(d) and the requirements referenced therein.[1]
2. Halogenated vent stream from a Group 1 storage tank.	You use a combustion control device to control organic HAP emissions.	Meet one of the emission limit options specified in Item 2.a.i or ii. in Table 1 to this subpart.

TABLE 4 TO SUBPART FFFF OF PART 63—EMISSION LIMITS FOR STORAGE TANKS—Continued

For each . . .	For which . . .	Then you must . . .
3. Storage tank of any capacity and vapor pressure.	Beginning no later than the compliance dates specified in § 63.2445(i), the stored liquid contains ethylene oxide such that the storage tank is considered to be in ethylene oxide service as defined in § 63.2550.	Comply with the applicable emission limits specified in items 1 and 2 of this Table, and also: i. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a flare; or ii. Reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a control device that reduces ethylene oxide by ≥99.9 percent by weight, or to a concentration <1 ppmv for each storage tank vent.

[1] Beginning no later than the compliance dates specified in § 63.2445(g), any flare using fuel gas from a fuel gas system, of which 50 percent or more of the fuel gas is derived from an MCPU that has processes and/or equipment in ethylene oxide service or that produces olefins or polyolefins, as determined on an annual average basis, must be in compliance with § 63.2450(e)(5). For purposes of compliance, an MCPU that ''produces olefins or polyolefins'' includes only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product. By-products and impurities as defined in § 63.101, as well as wastes and trace contaminants, are not considered products.

■ 28. Table 5 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2475, you must meet each emission limit and work practice standard in the following table that applies to your transfer racks:

TABLE 5 TO SUBPART FFFF OF PART 63—EMISSION LIMITS AND WORK PRACTICE STANDARDS FOR TRANSFER RACKS

For each . . .	You must . . .
1. Group 1 transfer rack	a. Reduce emissions of total organic HAP by ≥98 percent by weight or to an outlet concentration ≤20 ppmv as organic HAP or TOC by venting emissions through a closed-vent system to any combination of control devices (except a flare); or b. Reduce emissions of total organic HAP by venting emissions through a closed-vent system to a flare; or c. Comply with the requirements in § 63.2450(e)(4), as applicable; and reduce emissions of total organic HAP by venting emissions to a fuel gas system or process in accordance with § 63.982(d) and the requirements referenced therein;[1] or d. Use a vapor balancing system designed and operated to collect organic HAP vapors displaced from tank trucks and railcars during loading and route the collected HAP vapors to the storage tank from which the liquid being loaded originated or to another storage tank connected by a common header.
2. Halogenated Group 1 transfer rack vent stream for which you use a combustion device to control organic HAP emissions.	a. Use a halogen reduction device after the combustion device to reduce emissions of hydrogen halide and halogen HAP by ≥99 percent by weight, to ≤0.45 kg/hr, or to ≤20 ppmv; or b. Use a halogen reduction device before the combustion device to reduce the halogen atom mass emission rate to ≤0.45 kg/hr or to a concentration ≤20 ppmv.

[1] Beginning no later than the compliance dates specified in § 63.2445(g), any flare using fuel gas from a fuel gas system, of which 50 percent or more of the fuel gas is derived from an MCPU that has processes and/or equipment in ethylene oxide service or that produces olefins or polyolefins, as determined on an annual average basis, must be in compliance with § 63.2450(e)(5). For purposes of compliance, an MCPU that ''produces olefins or polyolefins'' includes only those MCPUs that manufacture ethylene, propylene, polyethylene, and/or polypropylene as a product. By-products and impurities as defined in § 63.101, as well as wastes and trace contaminants, are not considered products.

■ 29. Table 6 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2480, you must meet each requirement in the following table that applies to your equipment leaks:

TABLE 6 TO SUBPART FFFF OF PART 63—REQUIREMENTS FOR EQUIPMENT LEAKS

For all . . .	And that is part of . . .	You must . . .
1. Equipment that is in organic HAP service.	a. Any MCPU	i. Comply with the requirements of subpart UU of this part and the requirements referenced therein, except as specified in § 63.2480(b) and (d) through (f); or ii. Comply with the requirements of subpart H of this part and the requirements referenced therein, except as specified in § 63.2480(b) and (d) through (f); or iii. Comply with the requirements of 40 CFR part 65, subpart F, and the requirements referenced therein, except as specified in § 63.2480(c), and (d) through (f).
2. Equipment that is in organic HAP service at a new source.	a. Any MCPU	i. Comply with the requirements of subpart UU of this part and the requirements referenced therein, except as specified in § 63.2480(b)(6) and (7), (e), and (f); or ii. Comply with the requirements of 40 CFR part 65, subpart F, except as specified in § 63.2480(c)(10) and (11), (e), and (f).
3. Equipment that is in ethylene oxide service as defined in § 63.2550.	a. Any MCPU	i. Beginning no later than the compliance dates specified in § 63.2445(i), comply with the requirements of subpart UU of this part and the requirements referenced therein, except as specified in § 63.2493(d) and (e); or

TABLE 6 TO SUBPART FFFF OF PART 63—REQUIREMENTS FOR EQUIPMENT LEAKS—Continued

For all . . .	And that is part of . . .	You must . . .
		ii. Beginning no later than the compliance dates specified in § 63.2445(i), comply with the requirements of subpart H of this part and the requirements referenced therein, except as specified in § 63.2493(d) and (e); iii. Beginning no later than the compliance dates specified in § 63.2445(i), comply with the requirements of 40 CFR part 65, subpart F, and the requirements referenced therein, except as specified in § 63.2493(d) and (e).

■ 30. Table 10 to subpart FFFF of part 63 is revised to read as follows:

As required in § 63.2490, you must meet each requirement in the following table that applies to your heat exchange systems:

TABLE 10 TO SUBPART FFFF OF PART 63—WORK PRACTICE STANDARDS FOR HEAT EXCHANGE SYSTEMS

For each . . .	You must . . .
Heat exchange system, as defined in § 63.101	a. Comply with the requirements of § 63.104 and the requirements referenced therein, except as specified in § 63.2490(b) and (c); or b. Comply with the requirements in § 63.2490(d).

■ 31. Table 12 to subpart FFFF of part 63 is revised to read as follows:

As specified in § 63.2540, the parts of the general provisions that apply to you are shown in the following table:

TABLE 12 TO SUBPART FFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFF

Citation	Subject	Explanation
§ 63.1	Applicability	Yes.
§ 63.2	Definitions	Yes.
§ 63.3	Units and Abbreviations	Yes.
§ 63.4	Prohibited Activities	Yes.
§ 63.5	Construction/Reconstruction	Yes.
§ 63.6(a)	Applicability	Yes.
§ 63.6(b)(1)–(4)	Compliance Dates for New and Reconstructed sources	Yes.
§ 63.6(b)(5)	Notification	Yes.
§ 63.6(b)(6)	[Reserved]	
§ 63.6(b)(7)	Compliance Dates for New and Reconstructed Area Sources That Become Major.	Yes.
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources	Yes.
§ 63.6(c)(3)–(4)	[Reserved]	
§ 63.6(c)(5)	Compliance Dates for Existing Area Sources That Become Major.	Yes.
§ 63.6(d)	[Reserved]	
§ 63.6(e)(1)(i)	Operation & Maintenance	Yes, before August 12, 2023. No, beginning on and after August 12, 2023. See § 63.2450(u) for general duty requirement.
§ 63.6(e)(1)(ii)	Operation & Maintenance	Yes, before August 12, 2023. No, beginning on and after August 12, 2023.
§ 63.6(e)(1)(iii)	Operation & Maintenance	Yes.
§ 63.6(e)(2)	[Reserved]	
§ 63.6(e)(3)(i), (iii), and (v) through (viii).	Startup, Shutdown, Malfunction Plan (SSMP)	Yes, before August 12, 2023, except information regarding Group 2 emission points and equipment leaks is not required in the SSMP, as specified in § 63.2525(j). No, beginning on and after August 12, 2023.
§ 63.6(e)(3)(iii) and (iv)	Recordkeeping and Reporting During SSM	No, see § 63.2525 for recordkeeping requirements and § 63.2520(e)(4) for reporting requirements.
§ 63.6(e)(3)(ix)	SSMP incorporation into title V permit	Yes, before August 12, 2023. No beginning on and after August 12, 2023.
§ 63.6(f)(1)	Compliance With Non-Opacity Standards Except During SSM.	No. See § 63.2445(g) through (i).
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.
§ 63.6(g)(1)–(3)	Alternative Standard	Yes.
§ 63.6(h)(1)	Compliance with Opacity Standards Except During SSM.	No. See § 63.2445(g) through (i).

TABLE 12 TO SUBPART FFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFF—Continued

Citation	Subject	Explanation
§ 63.6(h)(2)–(9)	Opacity/Visible Emission (VE) Standards	Only for flares for which Method 22 of 40 CFR part 60, appendix A–7, observations are required as part of a flare compliance assessment.
§ 63.6(i)(1)–(14), and (16)	Compliance Extension	Yes.
§ 63.6(j)	Presidential Compliance Exemption	Yes.
§ 63.7(a)(1)–(2)	Performance Test Dates	Yes, except substitute 150 days for 180 days.
§ 63.7(a)(3)	Section 114 Authority	Yes, and this paragraph also applies to flare compliance assessments as specified under § 63.997(b)(2).
§ 63.7(a)(4)	Force Majeure	Yes.
§ 63.7(b)(1)	Notification of Performance Test	Yes.
§ 63.7(b)(2)	Notification of Rescheduling	Yes.
§ 63.7(c)	Quality Assurance/Test Plan	Yes, except the test plan must be submitted with the notification of the performance test if the control device controls batch process vents.
§ 63.7(d)	Testing Facilities	Yes.
§ 63.7(e)(1)	Conditions for Conducting Performance Tests	Yes, before August 12, 2023 except that performance tests for batch process vents must be conducted under worst-case conditions as specified in § 63.2460. No, beginning on and after August 12, 2023. See § 63.2450(g)(6).
§ 63.7(e)(2)	Conditions for Conducting Performance Tests	Yes.
§ 63.7(e)(3)	Test Run Duration	Yes.
§ 63.7(e)(4)	Administrator's Authority to Require Testing	Yes.
§ 63.7(f)	Alternative Test Method	Yes.
§ 63.7(g)	Performance Test Data Analysis	Yes, except this subpart specifies how and when the performance test and performance evaluation results are reported.
§ 63.7(h)	Waiver of Tests	Yes.
§ 63.8(a)(1)	Applicability of Monitoring Requirements	Yes.
§ 63.8(a)(2)	Performance Specifications	Yes.
§ 63.8(a)(3)	[Reserved]	
§ 63.8(a)(4)	Monitoring with Flares	Yes, except for flares subject to § 63.2450(e)(5).
§ 63.8(b)(1)	Monitoring	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems	Yes.
§ 63.8(c)(1)	Monitoring System Operation and Maintenance	Yes.
§ 63.8(c)(1)(i)	Routine and Predictable SSM	Yes, before August 12, 2023. No, beginning on and after August 12, 2023.
§ 63.8(c)(1)(ii)	CMS malfunction not in SSM plan	Yes.
§ 63.8(c)(1)(iii)	Compliance with Operation and Maintenance Requirements.	Yes, before August 12, 2023. No, beginning on and after August 12, 2023.
§ 63.8(c)(2)–(3)	Monitoring System Installation	Yes.
§ 63.8(c)(4)	CMS Requirements	Only for CEMS. Requirements for CPMS are specified in referenced subparts G and SS of this part. Requirements for COMS do not apply because this subpart does not require continuous opacity monitoring systems (COMS).
§ 63.8(c)(4)(i)	COMS Measurement and Recording Frequency	No; this subpart does not require COMS.
§ 63.8(c)(4)(ii)	CEMS Measurement and Recording Frequency	Yes.
§ 63.8(c)(5)	COMS Minimum Procedures	No. This subpart does not contain opacity or VE limits.
§ 63.8(c)(6)	CMS Requirements	Only for CEMS; requirements for CPMS are specified in referenced subparts G and SS of this part. Requirements for COMS do not apply because this subpart does not require COMS.
§ 63.8(c)(7)–(8)	CMS Requirements	Only for CEMS. Requirements for CPMS are specified in referenced subparts G and SS of this part. Requirements for COMS do not apply because this subpart does not require COMS.
§ 63.8(d)(1)	CMS Quality Control	Only for CEMS.
§ 63.8(d)(2)	CMS Quality Control	Only for CEMS.
§ 63.8(d)(3)	CMS Quality Control	Yes, only for CEMS before August 12, 2023. No, beginning on and after August 12, 2023. See § 63.2450(j)(6).
§ 63.8(e)	CMS Performance Evaluation	Only for CEMS, except this subpart specifies how and when the performance evaluation results are reported. Section 63.8(e)(5)(ii) does not apply because this subpart does not require COMS.
§ 63.8(f)(1)–(5)	Alternative Monitoring Method	Yes, except you may also request approval using the precompliance report.
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	Only applicable when using CEMS to demonstrate compliance, including the alternative standard in § 63.2505.

TABLE 12 TO SUBPART FFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFF—Continued

Citation	Subject	Explanation
§ 63.8(g)(1)–(4)	Data Reduction	Only when using CEMS, including for the alternative standard in § 63.2505, except that the requirements for COMS do not apply because this subpart has no opacity or VE limits, and § 63.8(g)(2) does not apply because data reduction requirements for CEMS are specified in § 63.2450(j).
§ 63.8(g)(5)	Data Reduction	No. Requirements for CEMS are specified in § 63.2450(j). Requirements for CPMS are specified in referenced subparts G and SS of this part.
§ 63.9(a)	Notification Requirements	Yes.
§ 63.9(b)(1)–(5)	Initial Notifications	Yes.
§ 63.9(c)	Request for Compliance Extension	Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Source.	Yes.
§ 63.9(e)	Notification of Performance Test	Yes.
§ 63.9(f)	Notification of VE/Opacity Test	No.
§ 63.9(g)	Additional Notifications When Using CMS	Only for CEMS. Section 63.9(g)(2) does not apply because this subpart does not require COMS.
63.9(h)(1)–(6)	Notification of Compliance Status	Yes, except § 63.9(h)(2)(i)(A) through (G) and (h)(2)(ii) do not apply because § 63.2520(d) specifies the required contents and due date of the notification of compliance status report.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes.
§ 63.9(j)	Change in Previous Information	No, § 63.2520(e) specifies reporting requirements for process changes.
§ 63.10(a)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(1)	Recordkeeping/Reporting	Yes.
§ 63.10(b)(2)(i)	Records related to startup and shutdown	No, see §§ 63.2450(e) and 63.2525 for recordkeeping requirements.
§ 63.10(b)(2)(ii)	Recordkeeping relevant to SSM periods and CMS	Yes, before August 12, 2023. No, beginning on and after August 12, 2023. See § 63.2525(h) and (l).
§ 63.10(b)(2)(iii)	Records related to maintenance of air pollution control equipment.	Yes.
§ 63.10(b)(2)(iv) and (v)	Recordkeeping relevant to SSM period	Yes, before August 12, 2023. No, beginning on and after August 12, 2023.
§ 63.10(b)(2)(vi)	CMS Records	Before August 12, 2023, yes but only for CEMS; requirements for CPMS are specified in referenced subparts G and SS of this part. Beginning on and after August 12, 2023, yes for CEMS and CPMS for flares subject to § 63.2450(e)(5).
§ 63.10(b)(2)(x) and (xi)	CMS Records	Only for CEMS; requirements for CPMS are specified in referenced subparts G and SS of this part.
§ 63.10(b)(2)(vii)–(ix)	Records	Yes.
§ 63.10(b)(2)(xii)	Records	Yes.
§ 63.10(b)(2)(xiii)	Records	Only for CEMS.
§ 63.10(b)(2)(xiv)	Records	Yes.
§ 63.10(b)(3)	Records	Yes.
§ 63.10(c)(1)–(6),(9)–(14)	Records	Only for CEMS. Recordkeeping requirements for CPMS are specified in referenced subparts G and SS of this part.
§ 63.10(c)(7)–(8)	Records	No. Recordkeeping requirements are specified in § 63.2525.
§ 63.10(c)(15)	Records	Yes, before August 12, 2023, but only for CEMS. No, beginning on and after August 12, 2023.
§ 63.10(d)(1)	General Reporting Requirements	Yes.
§ 63.10(d)(2)	Report of Performance Test Results	Yes, before October 13, 2020. No, beginning on and after October 13, 2020.
§ 63.10(d)(3)	Reporting Opacity or VE Observations	No.
§ 63.10(d)(4)	Progress Reports	Yes.
§ 63.10(d)(5)(i)	Periodic Startup, Shutdown, and Malfunction Reports	No, § 63.2520(e)(4) and (5) specify the SSM reporting requirements.
§ 63.10(d)(5)(ii)	Immediate SSM Reports	No.
§ 63.10(e)(1)	Additional CEMS Reports	Yes.
§ 63.10(e)(2)(i)	Additional CMS Reports	Only for CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.10(e)(2)(ii)	Additional COMS Reports	No. This subpart does not require COMS.
§ 63.10(e)(3)	Reports	No. Reporting requirements are specified in § 63.2520.
§ 63.10(e)(3)(i)–(iii)	Reports	No. Reporting requirements are specified in § 63.2520.
§ 63.10(e)(3)(iv)–(v)	Excess Emissions Reports	No. Reporting requirements are specified in § 63.2520.
§ 63.10(e)(3)(iv)–(v)	Excess Emissions Reports	No. Reporting requirements are specified in § 63.2520.
§ 63.10(e)(3)(vi)–(viii)	Excess Emissions Report and Summary Report	No. Reporting requirements are specified in § 63.2520.

TABLE 12 TO SUBPART FFFF OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFF—Continued

Citation	Subject	Explanation
§ 63.10(e)(4)	Reporting COMS data	No.
§ 63.10(f)	Waiver for Recordkeeping/Reporting	Yes.
§ 63.11	Control device requirements for flares and work practice requirements for equipment leaks.	Yes, except for flares subject to § 63.2450(e)(5).
§ 63.12	Delegation	Yes.
§ 63.13	Addresses	Yes.
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

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Part IV

Environmental Protection Agency

40 CFR Part 97

Promulgation of Air Quality Implementation Plans; State of Texas; Regional Haze and Interstate Visibility Transport Federal Implementation Plan; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[EPA–R06–OAR–2016–0611; FRL–10010–52–Region 6]

Promulgation of Air Quality Implementation Plans; State of Texas; Regional Haze and Interstate Visibility Transport Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the federal Clean Air Act (CAA or Act), the Environmental Protection Agency (EPA) is finalizing its affirmation, with amendments, of an intrastate sulfur dioxide (SO_2) trading program as an alternative to best available retrofit technology (BART) requirements for certain sources in Texas. This action finalizes the August 2018 proposed affirmation and November 2019 supplemental notice of proposed rulemaking (SNPRM) concerning certain aspects of a final rule published on October 17, 2017, partially approving the 2009 Texas Regional Haze State Implementation Plan (SIP) submission and promulgating a Federal Implementation Plan (FIP) for Texas to address certain outstanding CAA regional haze requirements for the first implementation period.

DATES: This final rule is effective on September 11, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2016–0611. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute therefore is not posted to *regulations.gov.* Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 6, 1201 Elm Street, Suite 500, Dallas, Texas 75270.

FOR FURTHER INFORMATION CONTACT: Jennifer Huser, Air and Radiation Division, Environmental Protection Agency, Region 6, 1201 Elm Street, Suite 500, Dallas, Texas 75270, telephone 214–665–7347; email address *Huser.Jennifer@epa.gov.*

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

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I. Background

A. Regional Haze

Regional haze is visibility impairment that is produced by a multitude of sources and activities that are located across a broad geographic area. These sources—both human-caused (anthropogenic) and naturally occurring—emit or otherwise introduce into the atmosphere PM, including fine PM ($PM_{2.5}$) (*e.g.,* sulfates, nitrates, organic carbon (OC), elemental carbon (EC), and soil dust), or pollutants that are precursors to the formation of $PM_{2.5}$ (*e.g.,* SO_2, NO_X, and, in some cases, ammonia (NH_3) and volatile organic compounds (VOCs)). Fine-particle precursors react in the atmosphere to form $PM_{2.5}$, which impairs visibility by scattering and absorbing light. Visibility impairment limits visual distance and reduces color, clarity, and contrast of view. Reducing $PM_{2.5}$ and its precursor gases in the atmosphere is an effective method of improving visibility. $PM_{2.5}$ can also cause serious health effects and mortality in humans and contributes to environmental effects, such as acid deposition and eutrophication.

Data from the existing visibility monitoring network, the ''Interagency Monitoring of Protected Visual Environments'' (IMPROVE) monitoring network, show that visibility impairment caused by air pollution occurs virtually all the time at most national parks and wilderness areas. In 1999, the average visual range [1] in many mandatory Class I areas [2] (*i.e.,* national parks and memorial parks, wilderness areas, and international parks meeting certain size criteria) in the western United States was 100–150 kilometers, or about one-half to two-thirds of the visual range that would exist without anthropogenic air pollution. In most of the eastern Class I areas of the United States, the average visual range was less than 30 kilometers, or about one-fifth of the visual range that would exist under estimated natural conditions.[3] Since the promulgation of the original Regional Haze Rule in 1999, CAA programs have reduced emissions of haze-causing pollution, lessening visibility impairment and resulting in improved average visual ranges.[4]

In Section 169A of the 1977 Amendments to the CAA, Congress created a program for protecting visibility in the nation's national parks

[1] Visual range is the greatest distance, in kilometers or miles, at which a dark object can be viewed against the sky.

[2] Areas designated as mandatory Class I Federal areas consist of National Parks exceeding 6,000 acres, wilderness areas and national memorial parks exceeding 5,000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the CAA, EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). The extent of a mandatory Class I area includes subsequent changes in boundaries, such as park expansions. 42 U.S.C. 7472(a). Although states and tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to ''mandatory Class I Federal areas.'' Each mandatory Class I Federal area is the responsibility of a ''Federal Land Manager.'' 42 U.S.C. 7602(i). When we use the term ''Class I area'' in this action, we mean a ''mandatory Class I Federal area.''

[3] 64 FR 35714 (July 1, 1999).

[4] An interactive ''story map'' depicting efforts and recent progress by EPA and states to improve visibility at national parks and wilderness areas may be visited at: *http://arcg.is/29tAbS3.*

and wilderness areas. This section of the CAA establishes as a national goal the prevention of any future, and the remedying of any existing, man-made impairment of visibility in 156 national parks and wilderness areas designated as mandatory Class I Federal areas. On December 2, 1980, EPA promulgated regulations to address visibility impairment in Class I areas that is ''reasonably attributable'' to a single source or small group of sources, *i.e.,* ''reasonably attributable visibility impairment.'' [5] These regulations represented the first phase in addressing visibility impairment. EPA deferred action on regional haze that emanates from a variety of sources until monitoring, modeling, and scientific knowledge about the relationships between pollutants and visibility impairment were improved.

Congress added section 169B to the CAA in 1990 to address regional haze issues, and we promulgated regulations addressing regional haze in 1999.[6] The Regional Haze Rule revised the existing visibility regulations to integrate into the regulations provisions addressing regional haze impairment and established a comprehensive visibility protection program for Class I areas. EPA's focus, following congressional direction, continued to be on three important visibility-impairing pollutants from relatively uncontrolled anthropogenic sources: Oxides of nitrogen (NO_X), sulfur dioxide (SO_2), and particulate matter (PM).[7] The requirements for regional haze, found at 40 CFR 51.308 and 51.309, are included in our visibility protection regulations at 40 CFR 51.300–309. The requirement to submit a regional haze SIP applies to all 50 states, the District of Columbia, and the Virgin Islands (referred to collectively hereafter as ''states''). States were required to submit their first SIP addressing regional haze visibility impairment no later than December 17, 2007.[8]

Section 169A(b)(2)(A) of the CAA directs states to evaluate the use of retrofit controls at certain larger, often under-controlled, older stationary sources in order to address visibility impacts from these sources. Specifically, section 169A(b)(2)(A) of the CAA requires states to revise their SIPs to contain such measures as may be necessary to make reasonable progress toward the natural visibility goal, including a requirement that certain categories of existing major stationary sources [9] built between 1962 and 1977 procure, install and operate best available retrofit technology (BART). Larger ''fossil-fuel fired steam electric plants'' are included among the statutory list of BART source categories at section 169A(g)(7). Under the Regional Haze Rule, states are directed to conduct BART determinations for ''BART-eligible'' sources that may be anticipated to cause or contribute to any visibility impairment in a Class I area. The evaluation of BART for EGUs that are located at fossil-fuel-fired power plants having a generating capacity in excess of 750 megawatts must follow the ''Guidelines for BART Determinations Under the Regional Haze Rule'' at appendix Y to 40 CFR part 51 (hereinafter referred to as the ''BART Guidelines''). States are required to identify the level of control representing BART after considering the five statutory factors set out in section 169A(g)(2).[10] States must establish emission limits, a schedule of compliance, and other measures consistent with the BART determination process for each source subject-to-BART.

Rather than requiring source-specific BART controls, states also have the flexibility to adopt an emissions trading program or alternative program as long as the alternative provides greater reasonable progress towards improving visibility than BART. 40 CFR 51.308(e)(2) specifies how a state must conduct the demonstration to show that an alternative program will achieve greater reasonable progress than the installation and operation of BART. 40 CFR 51.308(e)(2)(i)(E) requires a determination under 40 CFR 51.308(e)(3) or otherwise based on the clear weight of evidence that the trading program or other alternative measure achieves greater reasonable progress than would be achieved through the installation and operation of BART at the covered sources. Specific criteria for determining if an alternative measure achieves greater reasonable progress than source-specific BART are set out in 40 CFR 51.308(e)(3); however, as noted above, under 40 CFR 51.308(e)(2)(i)(E) states have the flexibility to develop their own criteria to establish greater reasonable progress based on the ''clear weight of the evidence.'' Finally, 40 CFR 51.308(e)(4) provides that states whose sources participate in the Cross-State Air Pollution Rule (CSAPR) trading programs need not require the BART-eligible fossil fuel-fired steam electric plants subject to those programs to install, operate, and maintain BART for the pollutant covered by the CSAPR trading program.

Regional haze requirements are generally implemented through the cooperative-federalism framework of section 110 of the Act, in which states are given the primary opportunity to meet the requirements through state implementation plans (SIPs). Under section 110(c) of the CAA, whenever we disapprove a mandatory SIP submission in whole or in part, or make a finding that a state has failed to make such a submission, we are required to promulgate a federal implementation plan (FIP) within two years unless the state corrects the deficiency and we approve the new SIP submittal.

B. Interstate Transport of Pollutants That Affect Visibility

Section 110(a) of the CAA directs states to submit a SIP that provides for the implementation, maintenance, and enforcement of each NAAQS. This is commonly referred to as an ''infrastructure SIP.'' CAA section 110(a)(2)(D)(i)(II) requires that infrastructure SIPs contain adequate provisions to prohibit interference with measures required to protect visibility in other states. This is referred to as ''interstate visibility transport'' (or ''prong 4'' of the four requirements or ''prongs'' found in section 110(a)(2)(D)(i)). Infrastructure SIPs are due to the EPA within three years after the promulgation of a new or revised NAAQS (or within such shorter period as we may prescribe). A state's failure to submit a complete, approvable infrastructure SIP, including one that meets the requirements for interstate visibility transport, creates an obligation for the EPA to address this requirement pursuant to section 110(c).

C. Previous Actions Related to Texas Regional Haze

On March 31, 2009, Texas submitted a regional haze SIP (the 2009 Regional Haze SIP) to the EPA that included reliance on Texas' participation in trading programs under the Clean Air Interstate Rule (CAIR) as an alternative to BART for SO_2 and NO_X emissions

[5] 45 FR 80084 (Dec. 2, 1980).

[6] 64 FR 35714 (July 1, 1999), codified at 40 CFR part 51, subpart P (Regional Haze Rule).

[7] *Id.* 35715.

[8] *See* 40 CFR 51.308(b). EPA's regional haze regulations require subsequent updates to the regional haze SIPs. 40 CFR 51.308(g)–(i).

[9] *See* 42 U.S.C. 7491(g)(7) (listing the set of ''major stationary sources'' potentially subject-to-BART).

[10] The State must take into consideration the five statutory factors: (1) The costs of compliance, (2) the energy and non-air quality environmental impacts of compliance, (3) any existing control technology in use at the source, (4) the remaining useful life of the source, and (5) the degree of visibility improvement which may reasonably be anticipated to result.

from EGUs.[11] This reliance was consistent with the EPA's regulations at the time that Texas developed its 2009 Regional Haze SIP.[12] However, at the time that Texas submitted this SIP to the EPA, the D.C. Circuit had remanded CAIR (without vacatur).[13] The court left CAIR and our CAIR FIPs in place in order to ''temporarily preserve the environmental values covered by CAIR'' until we could, by rulemaking, replace CAIR consistent with the court's opinion. The EPA promulgated the Cross-State Air Pollution Rule (CSAPR) to replace CAIR in 2011 [14] (and revised it in 2012).[15] CSAPR established FIP requirements for sources in a number of states, including Texas, to address the states' interstate transport obligation under CAA section 110(a)(2)(D)(i)(I). CSAPR addresses interstate transport of fine particulate matter and ozone by requiring affected EGUs in these states to participate in one or more of the CSAPR trading programs, which establish emissions budgets that apply to the EGUs' collective annual emissions of SO_2 and NO_X, as well as emissions of NO_X during ozone season.[16]

Following issuance of CSAPR, the EPA determined that CSAPR would achieve greater reasonable progress towards improving visibility than would source-specific BART in CSAPR states (a determination often referred to as ''CSAPR Better-than-BART'').[17] In the same action, we revised the Regional Haze Rule to allow states whose sources participate in the CSAPR trading programs to rely on such participation in lieu of requiring BART-eligible EGUs in the state to install BART controls as to the relevant pollutant.

In the same action that EPA determined that states could rely on CSAPR to address the BART requirements for EGUs, EPA issued a limited disapproval of a number of states' regional haze SIPs, including the 2009 Regional Haze SIP submittal from Texas, due to the states' reliance on CAIR, which had been replaced by CSAPR.[18] The EPA did not immediately promulgate a FIP to address those aspects of the 2009 Regional Haze SIP submittal subject to the limited disapproval of Texas' regional haze SIP to allow more time for the EPA to assess the remaining elements of the 2009 Texas SIP submittal.

In December 2014, we proposed an action to address the remaining regional haze obligations for Texas.[19] In that action, we proposed, among other things, to rely on our CSAPR FIP requiring Texas sources' participation in the CSAPR trading programs to satisfy the NO_X and SO_2 BART requirements for Texas' BART-eligible EGUs; we also proposed to approve the portions of the 2009 Regional Haze SIP addressing PM BART requirements for the state's EGUs. Before that rule was finalized, however, the D.C. Circuit issued a decision on a number of challenges to CSAPR, denying most claims, but remanding the CSAPR SO_2 and/or seasonal NO_X emissions budgets of several states to the EPA for reconsideration, including the Phase 2 SO_2 and seasonal NO_X budgets for Texas.[20] Due to the uncertainty arising from the remand of Texas' CSAPR budgets, we did not finalize our December 2014 proposal to rely on CSAPR to satisfy the SO_2 and NO_X BART requirements for Texas EGUs.[21] Additionally, because our proposed action on the PM BART provisions for EGUs was dependent on how SO_2 and NO_X BART were satisfied, we did not take final action on the PM BART elements of the 2009 Texas' Regional Haze SIP.[22] In January 2016, we finalized action on the remaining aspects of the December 2014 proposal.[23] This final action disapproved, among other things, Texas' Reasonable Progress Goals for the Big Bend and Guadalupe Mountains Class I areas in Texas, Texas's reasonable progress analysis and Texas's long-term strategy. EPA promulgated a FIP establishing a new long-term strategy that consisted of SO_2 emission limits for 15 coal-fired EGUs at eight power plants. That rulemaking was judicially challenged, however, and in July 2016, the Fifth Circuit granted the petitioners' motion to stay the rule pending review.[24] On March 22, 2017, following the submittal of a request by the EPA for a voluntary remand of the parts of the rule under challenge, the Fifth Circuit Court of Appeals remanded the rule in its entirety.[25]

On October 26, 2016, the EPA finalized an update to CSAPR to address the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) with respect to the 2008 ozone NAAQS (CSAPR Update).[26] The EPA also responded to the D.C. Circuit's remand in *EME Homer City II* of certain CSAPR seasonal NO_X budgets in that action. As to Texas, the EPA withdrew Texas' seasonal NO_X budget finalized in CSAPR to address the 1997 ozone NAAQS. However, in that same action, the EPA promulgated a FIP with a revised seasonal NO_X budget for Texas to address the 2008 ozone NAAQS.[27] Accordingly, Texas sources remain subject to CSAPR seasonal NO_X requirements.

On November 10, 2016, in response to the D.C. Circuit's remand of Texas's CSAPR SO_2 budget, we proposed to withdraw the FIP provisions that required EGUs in Texas to participate in the CSAPR trading programs for annual emissions of SO_2 and NO_X.[28] We also proposed to reaffirm the EPA's 2012 analytical demonstration that CSAPR provides greater reasonable progress than BART, despite changes in CSAPR's geographic scope to address the *EME Homer City II* remand, including removal of Texas' EGUs from the CSAPR trading program for SO_2 emissions. On September 29, 2017, we finalized the withdrawal of the FIP provisions for annual emissions of SO_2 and NO_X for EGUs in Texas [29] and affirmed our proposed finding that the EPA's 2012 analytical demonstration remains valid and that participation in the CSAPR trading programs as they now exist meets the Regional Haze Rule's criteria for an alternative to BART. (We refer to this as the ''2017 CSAPR Better-than-BART affirmation finding'' throughout this notice.) As discussed in Section I.D below, certain environmental organizations filed a petition for reconsideration of this finding in November 2017.

On January 4, 2017, we proposed a FIP to address the EGU BART

[11] CAIR required certain states, including Texas, to reduce emissions of SO_2 and NO_X that significantly contribute to downwind nonattainment of the 1997 NAAQS for fine particulate matter and ozone. See 70 FR 25152 (May 12, 2005).

[12] *See* 70 FR 39104 (July 6, 2005).

[13] *See North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), *as modified,* 550 F.3d 1176 (D.C. Cir. 2008).

[14] 76 FR 48207 (Aug. 8, 2011).

[15] CSAPR was amended three times in 2011 and 2012 to add five states to the seasonal NO_X program and to increase certain state budgets. 76 FR 80760 (December 27, 2011); 77 FR 10324 (February 21, 2012); 77 FR 34830 (June 12, 2012).

[16] The ozone season for CSAPR purposes is May 1 through September 30.

[17] 77 FR 33641 (June 7, 2012). This determination was recently upheld by the D.C. Circuit. *See Util. Air Regulatory Grp.* v. *EPA,* 885 F.3d 714 (D.C. Cir. 2018).

[18] *Id.*

[19] 79 FR 74818 (Dec. 16, 2014).

[20] EME Homer City Generation, *L.P.* v. *EPA* (EME Homer City II), 795 F.3d 118, 132 (D.C. Cir. 2015).

[21] *See* 81 FR 296, 301–02 (Jan. 5, 2016).

[22] *Id.*

[23] 81 FR 296 (Jan. 5, 2016).

[24] *Texas* v. *EPA,* 829 F.3d 405 (5th Cir. 2016).

[25] Order, *Texas* v. *EPA,* 16–60118 (5th Cir. Mar. 22, 2017).

[26] 81 FR 74504 (Oct. 26, 2016).

[27] *Id.* 74524–25.

[28] 81 FR 78954 (Nov. 10, 2016).

[29] 82 FR 45481 (Sept. 29, 2017). As explained above, Texas sources continue to be subject to the CSAPR Update FIP, under which they participate in a CSAPR trading program for ozone season NO_X.

requirements for Texas' EGUs. With respect to NO_X, we proposed to replace the 2009 Regional Haze SIP's reliance on CAIR with reliance on our CSAPR FIP to address the NO_X BART requirements for EGUs.[30] This portion of our proposal was based on the CSAPR Update and our separate November 10, 2016 proposed finding, described above, that the EPA's actions in response to the D.C. Circuit's remand would not adversely impact our 2012 demonstration that participation in the CSAPR trading programs meets the Regional Haze Rule's criteria for alternatives to BART. We noted that we could not finalize this portion of our proposed FIP to address the NO_X BART requirements for EGUs unless and until we finalized our proposed finding that CSAPR was still better than BART.[31] (This predicate finding was finalized on September 29, 2017, as described above.)

With respect to SO_2, our January 4, 2017 proposed action addressing the BART requirements for Texas EGUs acknowledged that because Texas sources would no longer be participating in the CSAPR program for SO_2, Texas would no longer be eligible to rely on participation in CSAPR as an alternative to source-specific EGU BART for SO_2 under 40 CFR 51.308(e)(4). As a result, there were BART requirements that were left unfulfilled with respect to Texas's BART-eligible EGU emissions of SO_2 that would need to be fulfilled by either an approved SIP or an EPA-issued FIP that satisfied the BART requirements under 40 CFR 51.308(e)(1) or constituted a viable BART alternative under 40 CFR 51.308(e)(2) for those emissions. EPA proposed to satisfy these requirements through a BART FIP, entailing the identification of BART-eligible EGU sources, screening to identify which BART-eligible sources are ''subject-to-BART'' (*i.e.,* may reasonably be anticipated to cause or contribute to any impairment of visibility in any Class I area), and source-by-source determinations of SO_2 BART controls as appropriate. For those EGU sources we proposed to find subject to BART, we proposed to promulgate source-specific SO_2 requirements. We proposed SO_2 emission limits on 29 EGUs located at 14 facilities.

With respect to PM, in the January 2017 proposal, we proposed to disapprove the portion of the 2009 Regional Haze SIP that made BART determinations for PM from EGUs, on the grounds that the demonstration in the 2009 Texas Regional Haze SIP relied on underlying assumptions as to how the SO_2 and NO_X BART requirements for EGUs were being met that were no longer valid with the proposed source-specific SO_2 requirements.[32] In place of these determinations, we proposed to promulgate source-specific PM BART requirements based on existing practices and control capabilities for those EGUs that we proposed to find subject to BART. Previously, we had proposed to approve the EGU BART determinations for PM in the 2009 Texas Regional Haze SIP, and this proposal had never been withdrawn.[33] At that time, CSAPR was an appropriate alternative for SO_2 and NO_X BART for EGUs. The 2009 Texas Regional Haze SIP included a pollutant-specific screening analysis for PM to demonstrate that Texas EGUs were not subject to BART for PM. In a 2006 guidance document,[34] the EPA stated that pollutant-specific screening can be appropriate where a state is relying on a BART alternative to address both NO_X and SO_2 BART. However, in the January 2017 proposal, we proposed to disapprove the PM BART determination since SO_2 BART was no longer addressed by a BART alternative. For coal-fired units, we proposed PM BART limits consistent with PM emission limits in the Mercury and Air Toxics Standards (MATS) rule; for gas-fired units, we proposed PM BART would be satisfied by making burning pipeline-quality gas federally enforceable; and for oil-fired units, we proposed that fuel-content requirements for SO_2 BART would also satisfy PM BART.[35]

In our final action addressing BART for Texas published on October 17, 2017, we finalized our January 2017 proposed determination that Texas' participation in CSAPR's trading program for ozone-season NO_X qualifies as an alternative to source-specific NO_X BART. We determined that the SO_2 BART requirements for all BART-eligible coal-fired units and a number of BART-eligible gas- or gas/fuel oil-fired units are satisfied by a BART alternative for SO_2—specifically, a new intrastate trading program that we established addressing emissions of SO_2 from certain EGUs in Texas. The remaining BART-eligible EGUs not covered by the SO_2 BART alternative were previously determined to be not subject to BART based on screening methods using model plants and CALPUFF[36] modeling as described in our proposed rule and BART Screening technical support document (TSD).[37] Finally, because both NO_X and SO_2 were now being addressed by a BART alternative, we approved the 2009 Regional Haze SIP's determination, based on a pollutant-specific screening analysis, that Texas' EGUs are not subject to BART for PM. With respect to visibility transport obligations, we determined that the BART alternative to address SO_2 and Texas sources' participation in CSAPR's trading program for ozone-season NO_X to address NO_X BART at Texas' EGUs fully addresses Texas' obligations for six NAAQS.

D. EPA's Denial of the Petition for Reconsideration of CSAPR as a BART Alternative and its Relationship to This Final Action

As explained in the section above, on September 29, 2017, we finalized the withdrawal of the CSAPR FIP provisions for annual emissions of SO_2 and NO_X for EGUs in Texas.[38] We also finalized our November 2016 proposed finding affirming that the EPA's 2012 analytical demonstration remains valid and that participation in the CSAPR

[30] 82 FR 912, 914–15 (Jan. 4, 2017).

[31] *Id.* 915.

[32] In the 2009 Regional Haze Texas SIP, for EGU BART, Texas' BART-eligible EGUs' emissions of both SO_2 and NO_X were covered by participation in trading programs, which allowed Texas to conduct a screening analysis of the visibility impacts from PM emissions from such units in isolation. However, modeling on a pollutant-specific basis for PM is appropriate only in the narrow circumstance of reliance on BART alternatives to satisfy both NO_X and SO_2 BART. Due to the complexity and nonlinear nature of atmospheric chemistry and chemical transformation among pollutants, EPA has not recommended performing modeling on a pollutant-specific basis to determine whether a source is subject to BART, except in the unique situation described above. See discussion in Memorandum from Joseph Paisie to Kay Prince, ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' July 19, 2006.

[33] 79 FR 74817, 74853–54 (Dec. 16, 2014).

[34] *See* discussion in Memorandum from Joseph Paisie to Kay Prince, ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' July 19, 2006.

[35] 82 FR 936.

[36] CALPUFF (California Puff Model) is a multi-layer, multi-species non-steady-state puff dispersion modeling system that simulates the effects of time- and space-varying meteorological conditions on pollutant transport, transformation, and removal. CALPUFF is intended for use in assessing pollutant impacts at distances greater than 50 kilometers to several hundreds of kilometers. It includes algorithms for calculating visibility effects from long range transport of pollutants and their impacts on Federal Class I areas. EPA previously approved the use of the CALPUFF model in BART related analyses (40 CFR part 51 Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations; Final Rule; 70 FR 39104—39172; July 6, 2005). For instructions on how to download the appropriate model code and documentation that are available from Exponent (Model Developer/Owner) at no cost for download, see EPA's website: *https://www.epa.gov/scram/air-quality-dispersion-modeling-preferred-and-recommended-models#calpuff.*

[37] See document at docket identification number EPA–R06–OAR–2016–0611–0005.

[38] 82 FR 45481 (Sept. 29, 2017).

trading programs continues to meet the Regional Haze Rule's criteria for an alternative to BART. In our October 17, 2017, action promulgating the Texas intrastate SO_2 trading program, we relied on that determination and the fact that the Texas program would achieve SO_2 emission reductions similar to what CSAPR would have achieved in Texas to conclude that the Texas program satisfies the requirements for a BART alternative under 40 CFR 51.308(e)(2).[39]

On November 28, 2017, Sierra Club and the National Parks Conservation Association submitted a petition for partial reconsideration of our September 2017 finding affirming that CSAPR continues to satisfy requirements as a BART alternative.[40] Among other things, these petitioners alleged that our analysis was materially flawed and must be reconsidered to the extent that it rested on an assumption that EGU BART sources in Texas would be subject to source-specific BART controls for SO_2 rather than the intrastate SO_2 trading program.[41] Petitioners alleged in particular that EPA's emissions shifting analysis accounted for potential increases in emissions in remaining CSAPR states of between 22,300 to 53,000 tons by assuming these emissions would be offset by an estimated 127,300 tons of SO_2 emission reductions in Texas due to source-specific BART controls.[42] However, these petitioners alleged that this assumption was proven false when EPA promulgated the Texas intrastate trading program rather than source-specific BART.[43] On this basis, among other things, petitioners sought mandatory reconsideration of the September 29, 2017 action under CAA section 307(d)(7)(B).

In a separate action, EPA is denying this petition for reconsideration.[44] That action, and the basis for that action as it relates to the determination that CSAPR remains a valid BART alternative, are beyond the scope of this action. With the denial of the petition for reconsideration of our 2017 affirmation in that separate action, EPA has made a final determination that the objections raised by the petitioners on the 2017 affirmation of CSAPR as a BART alternative are not of central relevance.[45] As such, there is no longer any outstanding question whether CSAPR is a satisfactory BART alternative. Therefore, as discussed in Section III.A.2 below, in this action EPA is finalizing its affirmation that it may rely on the CSAPR BART-alternative analysis as a part of its ''clear weight of the evidence'' demonstration that the Texas intrastate trading program achieves greater reasonable progress than BART.

II. Our Proposed Actions

A. Proposed Rule Affirming the October 2017 Final Action

On December 15, 2017, EPA received a petition for reconsideration of the October 2017 final rule addressing BART in Texas requesting that the Administrator reconsider certain aspects of the FIP related to the intrastate trading program promulgated to address the SO_2 BART requirement for Texas EGUs. In our April 30, 2018 letter in response to that petition, we stated that we believed that certain aspects of the federal plan could benefit from further public comment. Accordingly, in a notice published on August 27, 2018, we proposed to affirm certain aspects of our SIP approval and of the FIP, and we provided the public with an opportunity to comment on those aspects, as well as other specified related issues.[46] Specifically, we took comment on the following elements, which effectively covered all of petitioners' central objections: (1) The proposal to affirm the October 2017 FIP establishing an intrastate trading program addressing emissions of SO_2 from certain EGUs in Texas as a BART alternative and the determination that this program satisfies the requirements for BART alternatives; (2) the proposal to affirm the finding that the BART alternatives in the October 2017 rulemaking to address SO_2 and NO_X BART at Texas' EGUs result in emission reductions adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for the following NAAQS: 1997 8-hour ozone, 1997 $PM_{2.5}$ (annual and 24-hour), 2006 $PM_{2.5}$ (24-hour), 2008 8-hour ozone, 2010 1-hour NO_2, and 2010 1-hour SO_2 NAAQS; and (3) the proposal to affirm our October 2017 approval of Texas' SIP determination that no sources are subject to BART for PM. The August 2018 affirmation proposed rule also solicited comment on the specific issues of whether recent shutdowns of sources included in the trading program and the merger of two owners of affected EGUs should impact the allocation methodology for certain SO_2 allowances. In addition to soliciting comment on the above elements and aforementioned specific issues, the August 2018 affirmation proposal also invited comment on additional issues that could inform our decision making with regard to the SO_2 BART obligations for Texas. First, we sought input on whether SO_2 BART would be better addressed through a source-by-source approach (source-specific BART), the October 2017 SO_2 trading program, or some other appropriate BART alternative. Second, EPA requested comment on whether a SIP-based program would serve Texas better than a FIP. Third, we requested public input on whether and how the SO_2 trading program finalized in the October 2017 final rule addresses the long-term strategy and reasonable progress requirements for Texas.

B. Supplemental Notice of Proposed Rulemaking

In response to certain comments received during the public comment period for the August 2018 proposal to affirm the October 2017 FIP, we proposed revisions to the Texas SO_2 Trading Program in a supplemental proposal published on November 14, 2019.[47] In the supplemental proposal, we proposed to make four sets of amendments to the Texas SO_2 Trading Program: (1) The addition of assurance provisions; (2) revisions to the Supplemental Allowance Pool allocation provisions; (3) termination of the opt-in provisions; and (4) revision of the allowance recordation provisions.

(1) Addition of Assurance Provisions. The Texas SO_2 Trading Program, as promulgated in October 2017, did not include an assurance level. In contrast to CSAPR, the Texas SO_2 Trading Program does not allow for sources to purchase allowances from sources in other states. Therefore, the number of allowances available to the Texas sources under the SO_2 trading program, as promulgated in October 2017, is limited by the total number of allowances allocated under the program. While this limits the average annual emissions under the program, we recognized that the potential use of

[39] 82 FR 48324, 48330, 48357 (Oct. 17, 2017).

[40] Sierra Club and National Parks Conservation Association, Petition for Partial Reconsideration of Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas; Final Rule; 82 FR 45,481 (Sept. 29, 2017); EPA–HQ–OAR–2016–0598; FRL–9968–46–OAR (Nov. 28, 2017).

[41] *See, e.g., id.* 6 (citing 82 FR 45494).

[42] *Id.* 13–14 (citing 82 FR 45493–94).

[43] *Id.*

[44] See U.S. EPA, Denial of Petition for Partial Reconsideration of ''Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas'' (82 FR 45481; Sept. 29, 2017) (EPA–HQ–OAR–2016–0598). A copy of the denial of petition letter sent to the petitioners and the denial of petition Notice of Availability (NOA) published in the **Federal Register** are available at Docket ID EPA–HQ–OAR–2016–0598.

[45] *Id.*

[46] 83 FR 43586.

[47] 84 FR 61850.

banked allowances and allowances allocated from the Supplemental Allowance Pool could allow for potentially significant year-to-year variability in emissions. In each of the CSAPR trading programs, EPA set an assurance level for each state in order to ensure that, despite the broad, interstate trading region, emissions reductions would be achieved appropriately in a geographically distributed way commensurate with states' ''good neighbor'' obligations as determined by EPA through its analysis under CAA section 110(a)(2)(D)(i)(I).[48] In order to maintain consistency with the CSAPR program and to provide additional support for our determination that SO_2 emissions under the Texas SO_2 Trading Program will remain below the requisite level on an annual basis, the EPA proposed to add assurance provisions to the Texas SO_2 Trading Program in the November 2019 supplemental proposal, setting the assurance level by relying on the same analysis and methodology that were used to set assurance levels in the original CSAPR rulemaking while accounting for the fact that the Texas SO_2 Trading Program is intrastate-only (*i.e.,* does not permit interstate trading). EPA proposed to set an assurance level for the Texas SO_2 Trading Program of 255,081 tons and proposed to impose a penalty surrender ratio of three allowances for each ton of emissions in any year in excess of the 255,081-ton assurance level.

EPA further proposed that this assurance level would strengthen our determination that the Texas program compares favorably to CSAPR in terms of stringency. EPA noted that its previous CSAPR Better-than-BART analysis relied on assuming annual SO_2 emissions from Texas EGUs of 317,100 tons. For certain EGUs not covered by the Texas program but that would have been subject to CSAPR, EPA made a conservative estimate of 35,000 tons of annual emissions. Adding this to the 255,081 ton assurance level produced an upper bound estimate of 290,081 tons of emissions, which EPA noted is below the 317,100 ton assumption used for CSAPR.[49]

(2) *Revisions to the Supplemental Allowance Pool Allocation Provisions.* 40 CFR 97.912 of the existing Texas SO_2 Trading Program regulations establishes how allowances are allocated from the Supplemental Allowance Pool to sources (collections of participating units at a facility) that have reported total emissions for that control period exceeding the total amounts of allowances allocated to the participating units at the source for that control period (before any allocation from the Supplemental Allowance Pool). While all other sources required to participate in the trading program have flexibility to transfer allowances among multiple participating units under the same owner/operator when planning operations, Coleto Creek consists of only one coal-fired unit, and at the time of our October 2017 FIP, was the only coal-fired unit in Texas owned and operated by Dynegy. To provide this source additional flexibility, in the trading program as it was promulgated in October 2017, Coleto Creek was allocated its maximum supplemental allocation from the Supplemental Allowance Pool as long as there are sufficient allowances in the Supplemental Allowance Pool available for allocation, and its actual allocation would not be reduced in proportion with any reductions made to the supplemental allocations to other sources. In our August 2018 proposal, we noted that Dynegy has merged with Vistra, which owns other units that are subject to the trading program. In the August 2018 proposal, we solicited comment on eliminating this additional flexibility for Coleto Creek in light of the recent change in ownership, and we received no adverse comments on such a change. Therefore, in the November 2019 supplemental proposal, we proposed to make this change to the regulations.[50]

Some comments on our August 2018 proposal also expressed the view that it would be more equitable to make allocations from the Supplemental Allowance Pool in proportion to each owner's total emissions in excess of the owner's total base allowance allocations instead of in proportion to each individual source's emissions in excess of the individual source's base allowance allocation. In the November 2019 supplemental proposal, EPA proposed to agree that this change would be equitable and noted that it would also be consistent with the rationale for proposing to eliminate the special flexibility in the existing regulations for Coleto Creek. Accordingly, EPA proposed to amend the Supplemental Allowance Pool allocation provisions to reflect this further change in the allocation methodology. EPA specifically requested comment on the proposed revisions to the Supplemental Allowance Pool allocation provisions.[51]

(3) Termination of the Opt-in Provisions. In response to a comment on the August 2018 proposal that asserted that the opt-in provisions weakened the functional equivalence of the Texas SO_2 Trading Program to CSAPR, EPA proposed to terminate the opt-in provisions in the Texas SO_2 Trading Program in the November 2019 supplemental proposal. We noted that our proposal to terminate the opt-in provisions is consistent with the supplemental proposal's overall objective of strengthening our finding that the Texas SO_2 Trading Program will result in SO_2 emission levels from Texas EGUs that are similar to or less than the emission levels from Texas EGUs that would have been realized from participation in the SO_2 trading program under CSAPR. EPA also specifically requested comment on the proposed termination of the opt-in provisions and solicited comment as to what other relevant provisions in the Texas SO_2 Trading Program may offset the commenter's concerns with the opt-in provisions.[52]

(4) *Revision of the Allowance Recordation Provisions.* In the November 2019 supplemental proposal, we also proposed to amend the language in the recordation provisions such that the Administrator can delay recordation of Texas SO_2 Trading Program allowances for the specified control periods only in the event that Texas submits a SIP revision *and EPA takes final action to approve it.* Under 40 CFR 97.921(a) of the Texas SO_2 Trading Program regulations as originally promulgated in October 2017, ''[t]he Administrator may delay recordation of Texas SO_2 Trading Program allowances for the specified control periods if the State of Texas submits a SIP revision before the recordation deadline.'' Similarly, under § 97.921(b), ''[t]he Administrator may delay recordation of the Texas SO_2 Trading Program allowances for the applicable control periods if the State of Texas submits a SIP revision by May 1 of the year of the applicable recordation deadline under this paragraph.'' The revisions we proposed in the November 2019 supplemental proposal are necessary to ensure that the program remains fully operational unless it is replaced by a SIP revision that is approved by EPA as meeting the SO_2 BART requirements for the covered units. EPA specifically requested comment on the proposed revisions to the allowance recordation provisions.[53]

[48] 76 FR 48208, 48265–66 (Aug. 8, 2011).

[49] 84 FR 61850, 61853.

[50] *Id.* 61855.

[51] *Id.*

[52] *Id.* 61855–56.

[53] *Id.* 61856.

Finally, the EPA noted that the proposed revisions to the Texas SO_2 Trading Program would strengthen the program in a manner that provides further support that it will achieve greater emission reductions than Texas had agreed to in consultations with other states in setting reasonable progress goals for Class I areas outside Texas for the first implementation period of the Regional Haze Rule. As a result, the EPA believed the proposed changes strengthened its conclusion that the Texas trading program, in conjunction with Texas' participation in the CSAPR ozone-season NO_X trading program, satisfies interstate visibility transport obligations under section 110(a)(2)(D)(i)(II) as to the six NAAQS identified above. The EPA solicited comment on this relationship.[54]

III. Summary of Our Final Decisions

A. Regional Haze

After carefully considering the comments we received on our August 27, 2018 proposed rule and our November 14, 2019 supplemental proposal, we are taking final action to affirm our determination that our October 2017 FIP that established an intrastate trading program addressing emissions of SO_2 from certain EGUs in Texas, as amended in this final action as described in section III.A.1 below, satisfies the Regional Haze Rule requirements for a BART alternative under 40 CFR 51.308(e)(2). We are taking final action to affirm our determination that the BART alternatives addressing SO_2 BART, as amended in this final action, and NO_X BART at Texas' EGUs are adequate to satisfy the interstate visibility transport requirements for six NAAQS. We are also taking final action to affirm our October 2017 approval of Texas' SIP determination that no sources are subject to BART for PM. A discussion of the amendments to the Texas SO_2 Trading Program we are finalizing in today's final action and explanation of how the trading program satisfies the regulatory requirements for BART alternatives are discussed below in sections III.A.1 and III.A.2, respectively. This final rule is promulgated pursuant to CAA section 307(d). This includes our affirmation of the several aspects of the FIP promulgating the Texas SO_2 Trading Program, amendments to certain provisions of the FIP, which are 307(d)-listed actions, *see* 307(d)(1)(B). In addition, EPA exercises its discretion under 307(d)(1)(V) to treat the affirmation of our approval of parts of the 2009 Texas Regional Haze SIP as also an action subject to 307(d) requirements and procedural protections.

1. Amendments to the Texas SO_2 Trading Program

In response to certain comments we received during the public comment period for the August 2018 proposal to affirm the October 2017 FIP, we proposed revisions to the Texas SO_2 Trading Program in a supplemental proposal published on November 14, 2019.[55] We proposed to make four sets of amendments to the Texas SO_2 Trading Program: (1) The addition of assurance provisions; (2) revisions to the Supplemental Allowance Pool allocation provisions; (3) termination of the opt-in provisions; and (4) revision of the allowance recordation provisions. We are finalizing these amendments to the Texas SO_2 Trading Program, with certain modifications. We are also correcting a 2-ton error we made in the allowance allocation for El Paso Electric's Newman Plant due to a unit-identification error, thereby increasing the trading program budget from 238,393 tons to 238,395 tons. The amendments we are finalizing in today's action strengthen the Texas SO_2 Trading Program and increase its consistency with CSAPR. These amendments are discussed in the paragraphs that follow.

Addition of Assurance Provisions. In order to maintain consistency with the CSAPR program and to provide additional support for our determination that SO_2 emissions under the Texas SO_2 Trading Program will remain below the requisite level on an annual basis, we are taking final action to add assurance provisions to the Texas SO_2 Trading Program. To set the assurance level, we are relying on the same analysis and methodology that were used to set assurance levels in the original CSAPR rulemaking while accounting for the fact that the Texas SO_2 Trading Program is intrastate-only (*i.e.,* does not permit interstate trading). As discussed in our supplemental proposal, EPA determined in the CSAPR rulemaking that, on a state-specific basis for Texas, the statistical percentage measure representing the maximum expected one-year deviation from the state's average annual fossil fuel consumption for electricity generation was seven percent.[56] Applying that same percentage to the current Texas SO_2 Trading Program budget, EPA is finalizing a variability limit for Texas at 16,688 tons, which is seven percent of the corrected trading budget of 238,395 tons. The assurance level we are finalizing is the sum of the budget and the variability limit, or 255,083 tons, and we are making this assurance level effective beginning with the 2021 compliance period and for each period thereafter. We are also taking final action to amend the Texas SO_2 Trading Program's regulations to impose a penalty surrender ratio of three allowances for each ton of emissions in any year in excess of the 255,083-ton assurance level. We are taking final action to impose the penalty proportionately to emissions from those groups of sources represented by a common designated representative that emit in excess of the groups' annual allocations of allowances. Thus, if the total emissions of all sources in the program in any year exceed the annual program budget by more than a variability limit of 16,688 tons, the emissions over the assurance level will trigger a requirement for some sources to surrender three allowances for each ton of emissions over the assurance level, providing a strong disincentive against emissions exceeding the assurance level.

We are taking final action to add new provisions at multiple locations in the Texas SO_2 Trading Program regulations at 40 CFR part 97, subpart FFFFF (40 CFR 97.901 through 97.935) to add these assurance provisions. In § 97.902, new definitions of several terms used in the assurance provisions (''assurance account,'' ''common designated representative,'' ''common designated representative's assurance level,'' and ''common designated representative's share'') are being added in this final action. New § 97.906(c)(2) and(c)(3)(ii) set forth the central requirement of the assurance provisions—namely, that if SO_2 emissions from all covered sources in 2021 or any subsequent year collectively exceed the program's assurance level, then the owners and operators of the groups of sources determined to be responsible for the collective exceedance would be required to surrender allowances totaling twice the amount of the exceedance by a specified deadline, in addition to the allowances surrendered to account for the sources' total emissions. New § 97.910(b) and (c) establish the variability limit that would be added to the trading program budget to determine the amount of the assurance level. New § 97.920(b) provides for the establishment of assurance accounts, when appropriate, to hold the additional allowances to be surrendered. New § 97.925 sets forth

[54] *Id.* 61856–57.

[55] 84 FR 61850 (Nov. 14, 2019).

[56] *Id.* 61853.

additional procedures for EPA's administration of and sources' compliance with the assurance provisions. In addition to adding the provisions discussed above, in §§ 97.906 and 97.920, we are also taking final action to renumber and update internal cross-references to reflect the added and renumbered paragraphs. Finally, we are making revisions to existing language at §§ 97.902 (definitions of ''general account'' and ''Texas SO_2 Trading Program allowance deduction''), 97.906(b)(2), 97.913(c), 97.926(b), 97.928(b), and renumbered 97.906(c)(4)(ii) to integrate the new assurance provisions with various existing provisions of the Texas program regulations.

As discussed in our November 2019 supplemental proposal, in addition to being consistent with the original CSAPR methodology for setting assurance levels, an assurance level set at 255,083 tons is appropriate for the Texas SO_2 Trading Program because it provides further support for our October 2017 finding that the Texas SO_2 Trading Program will result in SO_2 emission levels from Texas EGUs that are similar to or less than the emission levels from Texas EGUs that would have been realized from participation in the SO_2 trading program under CSAPR. Additionally, at an assurance level of 255,083 tons of emissions annually, EPA has high confidence that emissions will be below the amount assumed in the BART-alternative sensitivity analysis utilized for the 2012 CSAPR Better-than-BART determination (*i.e.,* 317,100 tons), and thus visibility levels at Class I areas impacted by sources in Texas are anticipated to be at least as good as the levels projected in the 2012 analysis that assumed Texas would be in the larger CSAPR SO_2 trading program.[57]

The language of the revisions to the Texas SO_2 Trading Program regulations we are finalizing in this final rulemaking would generally parallel the analogous language from the CSAPR regulations at 40 CFR part 97, subparts AAAAA through EEEEE, streamlined to reflect the Texas program's narrower applicability (*i.e.,* specific units located only in Texas, excluding any new units built either in Texas or in Indian country within Texas' borders). The only substantive differences from the analogous CSAPR assurance provisions concern the approach used to impute allocation amounts—for use in apportioning responsibility for any collective exceedance of the assurance level—to any units that do not receive actual allowance allocations from the trading program budget. Under CSAPR, the only units potentially in this situation are new units that do not receive allowance allocations from the CSAPR new unit set-asides. The CSAPR regulations include a methodology for computing unit-specific imputed allocation amounts based on several data elements relating to the new units' design and potential operation.[58] In contrast, under the Texas SO_2 Trading Program, the only units potentially in this situation would be existing units that have ceased operation for an extended period, thereby losing their allocations from the trading budget under § 97.911(a), and that subsequently resume operation.[59] Because the Texas SO_2 Trading Program regulations already identify the unit-specific allowance allocations that these units would formerly have received from the trading budget, the Texas SO_2 Trading Program assurance provisions we are finalizing in this final rulemaking would use these previously established amounts for purposes of assurance provision calculations instead of requiring new imputed allocation amounts to be computed according to the more complex methodology in the CSAPR assurance provisions. The simpler approach we are finalizing for the Texas SO_2 Trading Program assurance provisions appears at paragraph (2) of the new definition of ''common designated representative's assurance level'' we are finalizing in § 97.902.

Revisions to the Supplemental Allowance Pool Allocation Provisions. All sources required to participate in the Texas SO_2 Trading Program have the flexibility to transfer allowances among multiple participating units under the same owner/operator when planning operations. As discussed in section II.B of this final action, the October 2017 final rule included additional flexibility to transfer allowances for Coleto Creek, but given the subsequent merger of Dynegy with Vistra, which owns other units that are subject to the trading program, Coleto Creek now has the same flexibility as other sources required to participate in the trading program to transfer allowances among multiple participating units under the same ownership when planning operations. In light of this, we are taking final action to eliminate the additional flexibility originally offered under the trading program for Coleto Creek.

We are also finalizing amendments to the methodology for allocating allowances from the Supplemental Allowance Pool such that allowance allocations are in proportion to each owner's total emissions in excess of the owner's total base allowance allocations instead of in proportion to each individual source's emissions in excess of the individual source's base allowance allocation. Comments we received on our August 2018 proposal and our November 2019 supplemental proposal generally indicated support for this change.[60] We find that this change would make the methodology for allocating allowances more equitable and is also consistent with the rationale for eliminating the special flexibility in the existing regulations for Coleto Creek. For consistency with the new variability limit of 16,688 tons, we are also reducing the number of allowances that can be allocated from the Supplemental Allowance Pool in any year to 16,688 tons plus any allowances added to the pool in that year from retired units. The effect of this revision is that the total number of allowances that can be issued in any year, considering both initial allocations and allowances issued from the Supplemental Allowance Pool, will not exceed the program's assurance level of 255,083 tons. This revision to the Supplemental Allowance Pool provisions is consistent with and reinforces the disincentive created by the assurance provisions against emissions exceeding the assurance level.

To implement these modifications to the Supplemental Allowance Pool, we are finalizing several revisions to §§ 97.911 and 97.912. In § 97.912, we are editing paragraph (a) to limit applicability of the current allocation methodology to the 2019 and 2020 control periods, and we are adding a new paragraph (b) that sets forth the revised allocation methodology for the control periods in 2021 and subsequent years. We are also renumbering two

[57] Id.

[58] *See, e.g.,* paragraph (3) of the definition of ''common designated representative's share'' at 40 CFR 97.702.

[59] Although the owners and operators of a unit in this situation might receive an allocation of allowances from the Supplemental Allowance Pool under § 97.912 based in part on the unit's emissions following resumption of operations, under the Texas program assurance provisions, any allocations of allowances from the Supplemental Allowance Pool would not be considered when apportioning responsibility for a collective exceedance of the assurance level.

[60] Supportive comments were submitted by most of the sources covered by the Texas SO_2 Trading Program, except for LCRA who did not specifically comment on the reduction in the number of allowances that can be allocated from the Supplemental Allowance Pool. Supportive comments can be found in the docket for this action at Document IDs EPA–R06–OAR–2016–0611–0157, EPA–R06–OAR–2016–0611–0127, EPA–R06–OAR–2016–0611–0163, EPA–R06–OAR–2016–0611–0156.

existing paragraphs of the section to accommodate the new paragraph (b) and are updating internal cross-references to reflect the renumbering and to integrate the provisions of the revised allocation methodology with other existing provisions. We are adding new § 97.912(b)(1) that addresses the revised allocation methodology and sets forth a procedure for assigning units into groups under common ownership called ''affiliated ownership groups.'' Under the new procedure, the group assignments will remain constant unless and until revised by EPA to reflect an ownership transfer. The initial group assignments for all covered units are specified in a new column that we are adding to the existing allowance allocation table in § 97.911(a)(1). Renumbered § 97.912(d) is revised to reduce the cap on the number of allowances that can be allocated from the Supplemental Allowance Pool for any given control period starting in 2021 to 16,688 tons plus any allowances added to the pool in that year from retired units. Existing § 97.912(a)(3)(ii)(B) is revised to add the same procedure included in new § 97.912(b)(4)(i)(C) for adjusting allocation amounts up or down by one allowance as needed to address rounding errors. Finally, we are finalizing non-substantive revisions to § 97.911(a)(2) and (c)(5) that clarify that allowances from the trading budget that are transferred to the Supplemental Allowance Pool are not necessarily ''allocated under'' § 97.912, but instead are made available for ''potential allocation in accordance with'' § 97.912.

Termination of Opt-in Provisions. To address concerns that the opt-in provisions weakened the functional equivalence of the Texas SO_2 Trading Program to CSAPR and to be consistent with EPA's determination not to include opt-in provisions in the CSAPR trading programs on the basis that opt-in provisions would undermine achievement of the CSAPR program's emission reduction objectives, we are taking final action to terminate the opt-in provisions in the Texas SO_2 Trading Program. As we discuss in the response to comments below, we find that this termination of the opt-in provisions will address concerns about the difficulty of distinguishing new emission reductions from reductions that opt-in sources would have made anyway, and the consequent likelihood that the amounts of allowances allocated to the sources would exceed their starting emissions levels and thus introduce ''extra'' allowances available to be traded to other sources. Our final action to terminate the opt-in provisions strengthens our finding that the Texas SO_2 Trading Program will result in SO_2 emission levels from Texas EGUs that are similar to or less than the emission levels from Texas EGUs that would have been realized from participation in the SO_2 trading program under CSAPR.

Because no units opted into the Texas SO_2 Trading Program for the 2019 or 2020 control periods and opting in is not allowed for any future control period, we are implementing our final action to terminate the opt-in provisions by removing the provisions from the regulations in their entirety. Specifically, §§ 97.904(b), 97.911(b), and 97.921(d), which concerned the procedure for opting in, allowance allocations for opt-in units, and recordation for opt-in units, respectively, are being removed. In addition, conforming revisions to reflect removal of the opt-in provisions are being made to the existing provisions at §§ 97.911(c)(5), 97.915(d), 97.930(b), 97.934(d)(1), and renumbered § 97.906(c)(3)(i).

Revision of Allowance Recordation Provisions. We are taking final action to condition any exceptions to scheduled allowance recordation activities on Texas' submission *and* EPA's approval of a SIP revision, rather than just on Texas' submission of a SIP revision. This revision will ensure that the program remains fully operational unless it is replaced by a SIP revision that is approved by EPA as meeting the SO_2 BART requirements for the covered units. To implement our final revision to the allowance recordation provisions, we are amending three paragraphs of § 97.921. In § 97.921(a), we are deleting without replacement the language providing for a possible delay of recordation activities scheduled for November 1, 2018; the language is moot because the recordation date has already passed. In § 97.921(b), which governs future recordation of allowances allocated from the trading budget under § 97.911(a), we are revising the existing language to provide that future recordation activities will take place as scheduled unless provided otherwise in EPA's approval of a SIP revision replacing the provisions of subpart FFFFF. We are also adding the same revised condition to § 97.921(c), which governs future recordation of allowances allocated from the Supplemental Allowance Pool under § 97.912.

Error Correction Adjusting the Allocation for El Paso Electric's Newman Plant. Our last amendment to the Texas SO_2 Trading Program regulations in this action corrects a small error in the allowance allocations and budget established in the October 2017 FIP. In our October 2017 action, we determined that several units at El Paso Electric's Newman plant (ORIS 3456) should be included in the Texas SO_2 Trading Program, including ''Newman unit 4.'' This ''unit'' is actually a multi-unit combined cycle system consisting of two gas- and oil-fired combustion turbine units serving a common steam turbine-generator. The combustion turbine units are identified in the databases used for the CSAPR SO_2 program as ''Newman unit **4'' and ''Newman unit **5.'' Both of these combustion turbine units are BART-eligible and both are properly included in the Texas SO_2 Trading Program pursuant to the evaluation of ''Newman unit 4'' set forth in our October 2017 action.[61] However, in establishing the allowance allocations and budgets in our October 2017 action, while we correctly accounted for the 2-ton CSAPR allocation to Newman unit **4, we mistakenly omitted the 2-ton CSAPR allocation to Newman unit **5. We are correcting our omission in this action. Specifically, in Table 1 in § 97.911(a)(1), we are relabeling the existing entry for ''Newman unit 4'' as ''Newman unit **4'' and adding a new entry for ''Newman unit **5'' with an additional 2-ton allocation, and in § 97.910(a)(1), we are increasing the Texas SO_2 Trading Program budget by 2 tons to 238,395 tons.[62] We find that these corrections are entirely consistent with the methodology and rationale we set forth when establishing the allocations and budget in our October 2017 action. Because the otherwise applicable recordation deadlines for the allowances allocated to Newman unit **5 for the control periods from 2019 through 2024 will have already passed by the effective date of this action, new § 97.921(f) establishes December 31, 2020 as the delayed recordation deadline for these allocations. Finally, language is added to § 97.912(a)(1) and (2) clarifying that allocations under § 97.911 are not considered in determining a source's eligibility to receive allocations from the Supplemental Allowance Pool unless the allocations have actually been recorded in the source's compliance account under § 97.921.

[61] See 82 FR at 48354–57, where we identify ''Newman unit 4'' as a BART-eligible source and discuss our evaluation for determining the inclusion of units in the Texas SO_2 Trading Program.

[62] Both Newman unit **4 and Newman unit **5 have participated in the Texas SO_2 Trading Program since January 1, 2019. El Paso Electric has monitored and reported the SO_2 emissions for both units under the program.

2. Analysis of Texas SO_2 Trading Program as a BART Alternative

We are taking final action to affirm our October 17, 2017 final action promulgating the Texas SO_2 Trading Program under 40 CFR 52.2312 and subpart FFFFF of part 97 as a BART alternative, with the amendments discussed in Section III.A.1. We are affirming our determination that the Texas SO_2 Trading Program, including the addition of the assurance provisions and other amendments to the program we are finalizing in this action, will result in future EGU emissions in Texas that will be less than the SO_2 emission levels used in the 2012 Better-than-BART demonstration for Texas EGU emissions assuming CSAPR participation.[63] Additionally, the aggregate visibility impact from Texas EGU emissions under the trading program will be similar to or less than what would have been realized from Texas participation in the CSAPR SO_2 trading program.[64] Further, on the basis of EPA's denial of a petition for reconsideration of the 2017 CSAPR Better-than-BART affirmation finding in a separate action,[65] EPA can now affirm that it has fully accounted for the stringency of the Texas program in the CSAPR Better-than-BART analysis (including accounting for the effects of Texas no longer being a part of the interstate trading region of CSAPR). We are taking final action to affirm our determination that the Texas SO_2 Trading Program satisfies the Regional Haze Rule requirements for BART alternatives, and therefore satisfies the SO_2 BART requirements for the BART-eligible coal-fired EGUs and gas- and gas/fuel oil-fired EGUs identified in the table below.

TABLE 1—TEXAS EGUS SUBJECT TO THE FIP SO_2 TRADING PROGRAM

Owner/operator	Units	BART-eligible
AEP	Welsh Power Plant Unit 1	Yes.
	Welsh Power Plant Unit 2	Yes.
	Welsh Power Plant Unit 3	No.
	H W Pirkey Power Plant Unit 1	No.
	Wilkes Unit 1 †	Yes.
	Wilkes Unit 2 †	Yes.
	Wilkes Unit 3 †	Yes.
CPS Energy	JT Deely Unit 1	Yes.
	JT Deely Unit 2	Yes.
	Sommers Unit 1 †	Yes.
	Sommers Unit 2 †	Yes.
LCRA	Fayette/Sam Seymour Unit 1	Yes.
	Fayette/Sam Seymour Unit 2	Yes.
Vistra	Big Brown Unit 1	Yes.
	Big Brown Unit 2	Yes.
	Coleto Creek Unit 1	Yes.
	Martin Lake Unit 1	Yes.
	Martin Lake Unit 2	Yes.
	Martin Lake Unit 3	Yes.
	Monticello Unit 1	Yes.
	Monticello Unit 2	Yes.
	Monticello Unit 3	Yes.
	Sandow Unit 4	No.
	Stryker Unit ST2 †	Yes.
	Graham Unit 2 †	Yes.
NRG	Limestone Unit 1	No.
	Limestone Unit 2	No.
	WA Parish Unit WAP4 †	Yes.
	WA Parish Unit WAP5	Yes.
	WA Parish Unit WAP6	Yes.
	WA Parish Unit WAP7	No.
Xcel	Tolk Station Unit 171B	No.
	Tolk Station Unit 172B	No.
	Harrington Unit 061B	Yes.
	Harrington Unit 062B	Yes.
	Harrington Unit 063B	No.
El Paso Electric	Newman Unit 2†	Yes.
	Newman Unit 3 †	Yes.
	Newman Unit **4 †	Yes.
	Newman Unit **5 †	Yes.

† Gas-fired or gas/fuel oil-fired units.

Under 40 CFR 51.308(e)(2), a State may opt to implement or require participation in an emissions trading program or other alternative measure rather than to require sources subject to BART to install, operate, and maintain BART. Among other things, such an emissions trading program or other alternative measure must achieve greater reasonable progress than would be achieved through the installation and operation of BART. In the paragraphs

[63] 83 FR 43586, 43591 (Aug. 27, 2018).

[64] *Id.* 43592.

[65] See U.S. EPA, Denial of Petition for Partial Reconsideration of ''Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas'' (82 FR 45481; Sept. 29, 2017) (EPA–HQ–OAR–2016–0598). A copy of the denial of petition letter sent to the petitioners and the denial of petition Notice of Availability (NOA) published in the **Federal Register** are available at Docket ID EPA–HQ–OAR–2016–0598.

that follow, we summarize the BART alternative requirements under § 51.308(e)(2) and explain how the Texas SO_2 Trading Program satisfies each requirement.

Section 51.308(e)(2)(i) requires a demonstration that the emissions trading program or other alternative measure will achieve greater reasonable progress than would have resulted from the installation and operation of BART at all sources subject to BART in the State and covered by the alternative program. This demonstration must be based on the criteria listed under § 51.308(e)(2)(i)(A) through (E).

Section 51.308(e)(2)(i)(A). As part of the demonstration that the emissions trading program or other alternative measure will achieve greater reasonable progress than BART, the Regional Haze Rule requires that a list of all BART-eligible sources within the state be provided. In our October 2017 final action, we finalized our list of all BART-eligible sources in Texas,[66] which serves to satisfy 51.308(e)(2)(i)(A). As explained in our August 27, 2018 affirmation proposal,[67] we did not reopen the identification of BART-eligible sources and thus did not request comment on this element.

Section 51.308(e)(2)(i)(B). This provision requires that a list of all BART-eligible sources and all BART source categories covered by the alternative program be provided. The regulations do not require inclusion of every BART source category or every BART-eligible source within a BART source category in an alternative program, but each BART-eligible source in the state must be subject to the requirements of the alternative program, have a federally enforceable emission limitation determined by the state and approved by EPA as meeting BART in accordance with section 302(c) or § 51.308(e)(1), or be otherwise addressed under § 51.308(e)(1) or (e)(4). Our October 2017 final action and our August 2018 affirmation proposal included a list of all EGUs covered by the trading program. We are finalizing our affirmation of the list of BART-eligible EGUs in Texas covered by the alternative program with one minor non-substantive change,[68] satisfying the first requirement of 51.308(e)(2)(i)(B). Table 1 above lists all participating units and identification of BART-eligible participating units. All BART-eligible coal-fired units, some additional coal-fired EGUs, and some BART-eligible gas-fired and oil-and-gas-fired units are covered by the alternative program. This coverage and our determination in a previous final action that the BART-eligible gas-fired and oil-and-gas-fired EGUs not covered by the program are not subject-to-BART for NO_X, SO_2 and PM satisfy the second requirement of 51.308(e)(2)(i)(B). We note that EPA's determination that these EGU units not covered by the program are not subject to BART was finalized in our October 2017 final action,[69] and we did not reopen that determination in the August 2018 proposal.[70]

Section 51.308(e)(2)(i)(C). This provision requires an analysis of the best system of continuous emission control technology available and associated emission reductions achievable for each source within the state subject to BART and covered by the alternative program. This analysis must be conducted by making a determination of BART for each source subject to BART and covered by the alternative program as provided for under § 51.308(e)(1), unless the emissions trading program or other alternative measure has been designed to meet a requirement other than BART. In such a case, the state may determine the best system of continuous emission control technology and associated emission reductions for similar types of sources within a source category based on both source-specific and category-wide information, as appropriate. As discussed in our August 2018 proposal, we considered the question of whether, in applying this portion of the Regional Haze Rule, we should take as the baseline the application of source-specific BART at the covered sources.[71] We have determined not to take this approach here, given that 51.308(e)(2)(i)(C) provides for an exception (which we are exercising) to the requirement for source-specific BART determinations for the covered sources. The regulations allow for the BART ''benchmark'' to be set using ''category-wide'' information when the alternative measure ''has been designed to meet a requirement other than BART (such as the core requirement to have a long-term strategy to achieve the reasonable progress goals established by States).'' *See* 40 CFR 51.308(e)(2)(i)(C). As discussed below, category-wide information may include, for example, the use of ''presumptive'' BART emission limits for a particular source category, such as coal-fired EGUs. The Texas SO_2 Trading Program meets the conditions of the exception allowed under § 51.308(e)(2)(i)(C), as discussed in sections III.B and V.B of this final notice, because it has been designed to meet Texas' interstate visibility transport requirements under CAA section 110(a)(2)(D)(i)(II). This BART alternative extends beyond all BART-eligible coal-fired units to include a number of additional coal-fired EGUs, and some BART-eligible gas-fired and oil-and-gas-fired units, capturing the majority of emissions from EGUs in the state, and is designed to provide the measures that are needed to address interstate visibility transport requirements for several NAAQS. This is because for all sources covered by the Texas SO_2 Trading Program, those sources' CSAPR allocations for SO_2 are incorporated into the BART alternative, and the Texas SO_2 Trading Program ensures more emission reductions of SO_2 than the level of emissions reductions relied upon by other states during consultation and assumed by other states in their own regional haze SIPs, including their reasonable progress goals for their Class I areas.

As allowed under § 51.308(e)(2)(i)(C), rather than using source-specific BART at the covered sources, we are relying on the determinations of BART and associated emission reductions for EGUs that were used in our 2012 determination that showed that CSAPR as finalized and amended in 2011 and 2012 achieves more reasonable progress than BART (''CSAPR Better-than-BART''). This analysis establishes by the clear weight of evidence that the Texas SO_2 Trading Program, which is modeled on the CSAPR trading programs, will provide for greater reasonable progress than BART in Texas. These determinations of the best system of continuous emission control technology and associated emission reductions for EGUs that were used in our 2012 CSAPR Better-than-BART demonstration were based largely on category-wide information, including the use of ''presumptive'' BART limits.[72] EPA finds that reliance on the category-wide BART analysis from the

[66] See 82 FR at 48356 (final action) and 82 FR at 918 (proposed action).

[67] 83 FR at 43598.

[68] As discussed in section III.A.2, ''Newman unit 4'' at the El Paso Electric Newman plant (ORIS 3456), which is included in the Texas SO_2 Trading Program, is actually a multi-unit combined cycle system consisting of two gas- and oil-fired combustion turbine units (Newman unit **4 and Newman unit **5) serving a common steam turbine-generator. Both of these combustion turbine units are BART-eligible, and both are properly included in the Texas SO_2 Trading Program. In this final action, we are not identifying any new units as BART-eligible, we are merely relabeling the already-identified BART-eligible ''Newman unit 4'' as its components: ''Newman unit **4'' and ''Newman unit **5.'' Thus, we do not consider this change to be substantive.

[69] 82 FR at 48328.

[70] 83 FR at 43598, footnote 80.

[71] 83 FR at 43599.

[72] 77 FR at 33649–50.

2012 CSAPR Better-than-BART demonstration is appropriate here and that the BART determinations derived from that CSAPR Better-than-BART demonstration are an appropriate BART benchmark for comparison against the Texas SO_2 Trading Program given that the Texas SO_2 Trading Program is modeled on the CSAPR trading programs.

We note that in our August 2018 proposal, we proposed to affirm our finding that the Texas SO_2 trading program is also designed to be part of the long-term strategy needed to meet the reasonable progress requirements of the Regional Haze Rule, which remain outstanding after the remand of our January 2016 FIP addressing Texas' reasonable progress obligations by the Fifth Circuit Court of Appeals. After consideration of the comments we received addressing this issue during the public comment period for our August 2018 proposal, we are not finalizing our affirmation of the finding that the Texas SO_2 trading program is also designed to be part of the long-term strategy needed to meet the reasonable progress requirements of the Regional Haze Rule at this time. While the Texas SO_2 trading program certainly contributes to reasonable progress toward meeting the visibility goals of the regional haze program through enforceable reductions of a visibility pollutant from baseline emission levels, EPA has made clear that it intends to address the specific regulatory requirements for the long-term strategy for Texas through a separate action.[73] However, this does not impact our determination that the Texas SO_2 trading program satisfies the requirements of section 51.308(e)(2)(i)(C) given that the trading program is designed to provide the measures that are needed to address interstate visibility transport requirements for several NAAQS, and this sufficiently meets the criteria under § 51.308(e)(2)(i)(C) allowing us to exercise the exception allowed under the provision. Thus, we have met the requirements of § 51.308(e)(2)(i)(C).

Section 51.308(e)(2)(i)(D). This provision requires an analysis of the projected emissions reductions achievable through the trading program or other alternative measure. Our analysis is that the Texas trading program will effectively limit the aggregate annual SO_2 emissions of the covered EGUs to be no higher than the assurance level of 255,083 tons. The Texas SO_2 Trading Program is an intrastate cap-and-trade program for listed covered sources in the State of Texas modeled after the EPA's CSAPR SO_2 Group 2 Trading Program. Authorizations to emit SO_2, known as allowances, are allocated to the affected units as listed in Table 1 above. As discussed elsewhere, the program includes a Supplemental Allowance Pool, as revised in this final action, with additional allowances that may be allocated to subject units and sources to provide compliance assistance. The average total annual allowance allocation for all covered sources is 238,395 tons, with an additional 10,000 tons allocated to the Supplemental Allowance Pool. In addition, while the Supplemental Allowance Pool may grow over time as unused supplemental allowances remain available and allocations from retired units are placed in the pool, the total number of allowances that can be allocated to sources in a control period from the supplemental pool beginning with the 2021 compliance period and for each period thereafter is limited to a maximum 16,688 tons plus the amount of any allowances placed in the pool that year from retired units and corrections. Therefore, the total annual average emissions for the covered sources will be less than or equal to 248,395 tons. Although there will be some year-to-year variability, that variability will be constrained by the addition of an assurance level in this final action. We are finalizing an assurance level of 255,083 tons per year for the Texas SO_2 Trading Program, which, in light of the three-for-one penalty surrender ratio imposed on emissions exceeding that level, represents the highest annual SO_2 emissions anticipated from units subject to the Texas program. In reality, there is no reasonable expectation that actual emissions would even approach this level in light of ongoing changes in the electric-generating sector in Texas.

Further, the projected average SO_2 emission reduction that will be achieved by the program in any given year, relative to any selected historical baseline year, would be the difference between the aggregate historical baseline emissions of the covered units and the average total annual allocation of 238,395 SO_2 tons plus a Supplemental Allowance Pool budget of 10,000 tons, or 248,395. As detailed in our October 2017 final rule, for the purpose of this analysis, we selected 2014 as the baseline year.[74] The aggregate 2014 SO_2 emissions of the covered EGUs were 309,298 tons per year, while the average total annual allocation for the covered EGUs is 238,395 SO_2 tons plus a Supplemental Allowance Pool budget of 10,000 tons, or 248,395 tons per year. Therefore, compared to 2014 emissions, the Texas trading program is projected to achieve an average reduction of approximately 60,903 tons per year from the covered units.[75] (We note that with the termination of the opt-in provisions in this final action, there is no need for this comparison to include consideration of the 2014 emissions from those units formerly eligible to opt into the trading program.)

We also note that the Regional Haze Rule provides that the baseline period for the first planning period is 2000–2004.[76] The Texas SO_2 Trading Program, with the assurance level we are finalizing in this action, achieves significantly lower emissions relative to the baseline period using 2002 as the baseline. As shown in Table 2, the total combined SO_2 emissions from Texas EGUs participating in the Texas SO_2 Trading Program were 515,526 tons in 2002. The combined actual SO_2 emissions from all Texas EGUs (both those in the Texas SO_2 Trading Program and those not in the program) were 562,516 tons in 2002.[77] By comparison, the Texas SO_2 Trading Program budget is 238,395 SO_2 tons (plus a Supplemental Allowance Pool budget of 10,000 tons). Thus for the covered units, the program achieves average annual emissions from the covered units of 248,395 tons. Compared with the 2002 baseline for these units, the program achieves 267,131 tons of reductions.

When we account for Texas units that were in CSAPR but not in the current program, we see a similar result using a conservative assumption about those units' emissions going forward. (As we explained in our supplemental proposal, our comparison of the Texas program to CSAPR should take account

[73] 83 FR at 43596 n.63.

[74] Texas sources were subject to the CSAPR SO_2 trading program in 2015 and 2016 but are no longer subject to that program. We therefore select 2014 as the appropriate most recent year for comparing the aggregate historical baseline emissions of the covered units to the average total annual allocation for purposes of estimating the SO_2 emission reduction that will be achieved by the program.

[75] We note that for other types of alternative programs that might be adopted under 40 CFR 51.308(e)(2), the analysis of achievable emission reductions could be more complicated. For example, a program that involved economic incentives instead of allowances or that involved interstate allowance trading would present a more complex situation in which achievable emission reductions could not be calculated simply by comparing aggregate baseline emissions to aggregate allowances.

[76] See 40 CFR 51.308(d)(2)(i).

[77] See Excel spreadsheet file ''Texas EGU 2002 SO_2 Emissions.xlsx,'' which is available in the docket for this action.

of emissions from these units.[78]) For illustrative purposes, in this comparison we will also use the higher figure of the assurance level for the Texas program rather than the average annual allocation. When our conservative assumption of 35,000 tons as the future combined SO_2 emissions for units that were in the CSAPR program but not covered by the Texas SO_2 Trading Program is added to the highest annual SO_2 emissions anticipated from units under the Texas SO_2 Trading Program, 255,083 tons per year (*i.e.,* the assurance level for the program), the total figure is 290,083 tons per year. A comparison of these figures reveals that the combined actual SO_2 emissions from all Texas EGUs in 2002 during the baseline period (562,516 tons) were considerably higher than the highest annual SO_2 emissions anticipated from all Texas EGUs anticipated from operation of the Texas SO_2 Trading Program (290,083 tons), including the CSAPR units not included in that program—a difference of 272,433 tons. The emission reductions that are secured by the Trading Program contribute to improvements in visibility from the baseline period and are permanent and enforceable as part of the long-term strategy for the State of Texas.

TABLE 2—2002 SO_2 EMISSIONS FROM TEXAS EGUS SUBJECT TO THE FIP SO_2 TRADING PROGRAM †

Owner/operator	Units	SO_2 emissions (tons)
AEP	Welsh Power Plant Unit 1	12,259
	Welsh Power Plant Unit 2	11,937
	Welsh Power Plant Unit 3	11,584
	H W Pirkey Power Plant Unit 1	19,476
	Wilkes Unit 1	1
	Wilkes Unit 2	2
	Wilkes Unit 3	3
CPS Energy	J T Deely Unit 1	9,936
	J T Deely Unit 2	11,577
	Sommers Unit 1	1
	Sommers Unit 2	2
LCRA	Fayette/Sam Seymour Unit 1	13,617
	Fayette/Sam Seymour Unit 2	16,401
Vistra	Coleto Creek Unit 1	14,288
	Big Brown Unit 1	43,413
	Big Brown Unit 2	34,448
	Martin Lake Unit 1	24,837
	Martin Lake Unit 2	22,539
	Martin Lake Unit 3	19,023
	Monticello Unit 1	28,643
	Monticello Unit 2	34,700
	Monticello Unit 3	22,976
	Sandow Unit 4	23,330
	Stryker ST2	43
	Graham Unit 2	23
NRG	Limestone Unit 1	17,009
	Limestone Unit 2	13,830
	W A Parish Unit WAP4	4
	W A Parish Unit WAP5	21,310
	W A Parish Unit WAP6	18,006
	W A Parish Unit WAP7	18,459
Xcel	Tolk Station Unit 171B	12,703
	Tolk Station Unit 172B	12,171
	Harrington Station Unit 061B	9,197
	Harrington Station Unit 062B	8,927
	Harrington Station Unit 063B	8,844
El Paso Electric	Newman Unit 2	1
	Newman Unit 3	1
	Newman Unit **4	1
	Newman Unit **5	1
Total Combined 2002 SO_2 Emissions.		515,526

† Based on 2002 Clean Air Markets Division (CAMD) data.

Section 51.308(e)(2)(i)(E). This provision requires a determination, under the specific criteria laid out at 40 CFR 51.308(e)(3) or otherwise based on the clear weight of evidence, that the trading program or other alternative measure achieves greater reasonable progress than would be achieved through the installation and operation of BART at the covered sources. The BART alternative EPA is taking final action to affirm here is supported by the clear weight of the evidence. Specifically, with respect to SO_2 emissions from the covered BART-eligible units, because the Texas SO_2 trading program, as amended, is designed to ensure that emissions levels in each year under the trading program are similar to or less than what would have been realized from Texas EGUs from participation in the SO_2 trading program under CSAPR, EPA can rely on the 2012 and 2017 findings that CSAPR achieves greater

[78] 84 FR at 61853.

reasonable progress than BART as evidence that the Texas program achieves greater reasonable progress than BART, in the context of the continued operation of the CSAPR ozone-season NO_X trading program (to which units in Texas remain subject) and the CSAPR annual NO_X and SO_2 trading programs.[79] As used in our 51.308(e)(2)(i)(D) analysis above and laid out in more detail below, a conservative estimate for the maximum total annual emissions from all EGUs in Texas that can be anticipated with the Texas program in place is 290,083 tons. As explained below, this is less than the maximum total annual emissions assumed for Texas under CSAPR in the CSAPR Better-than-BART analysis, which is 317,100 tons. Thus, we are relying on the demonstration in the 2012 and 2017 CSAPR Better-than-BART rules (as reaffirmed in the separate denial of petition for reconsideration of the 2017 rule) to show that the clear weight of evidence demonstrates that the Texas SO_2 Trading Program, which is modeled on the CSAPR trading programs, provides for greater reasonable progress than BART in Texas.

Because the Texas program is designed to achieve greater SO_2 emission reductions than CSAPR in Texas, we are finalizing our affirmation that it is appropriate to continue to rely on the 2012 CSAPR Better-than-BART demonstration, which includes the treatment of Texas as a CSAPR state, as reaffirmed in September 2017 (and again affirmed in EPA's denial of the November 28, 2017 petition for reconsideration, as discussed under section I.D of this final action [80]). That analysis compared CSAPR in Texas and elsewhere in the country to presumptive BART emission limits for the sources in Texas (as elsewhere) and is described in greater detail in our August 2018 proposed affirmation. *See* 83 FR 43586, at 43594–95. While Texas is no longer in the CSAPR trading program for SO_2 itself, we find that it is appropriate for us to continue relying here on the CSAPR Better-than-BART analysis for Texas given that the Texas SO_2 Trading Program is specifically designed to mimic the CSAPR program and the amendments to the Texas trading program EPA is finalizing in this action allow EPA to affirm that the Texas program is similar to or more stringent than CSAPR in Texas. As such, the stringency of the Texas program is sufficient to allow for the continued use of the CSAPR Better-than-BART analysis for Texas.

Although it is not within the scope of this action, EPA notes that the 2017 CSAPR Better-than-BART finding has been reaffirmed through the denial of a petition for reconsideration.[81] In our response to the petition for reconsideration, EPA explains that it has fully accounted for the stringency of the Texas trading program as well as the potential for emission shifting back into the remaining CSAPR region with the removal of Texas into its own intrastate trading region.[82] To the extent that this potential for emission shifting posed any concern that the CSAPR Better-than-BART analysis could not be relied upon by Texas or other states, this issue has been resolved through the analysis set forth in that denial.

We are finalizing our determination that anticipated maximum potential SO_2 emissions in Texas under the Texas SO_2 Trading Program BART alternative are less than the SO_2 emission levels from Texas EGUs that were forecast in the CSAPR Better-than-BART demonstration assuming their participation in the CSAPR SO_2 trading program.[83] In our October 2017 final rule and the August 2018 proposal to affirm that rule, we noted the results of the sensitivity analysis [84] for the 2012 final ''CSAPR Better-than-BART'' rulemaking, namely that CSAPR was expected to provide for greater reasonable progress than BART nationwide even with potential SO_2 emissions from Texas EGUs under CSAPR as high as 317,100 tons.[85] In our October 2017 final rule and the August 2018 proposal to affirm that rule, EPA used this benchmark (317,100 tons of SO_2 emissions per year) to gauge whether the Texas SO_2 Trading Program was sufficiently stringent for EPA to continue to rely on the BART-alternative analysis we conducted in the 2012 ''CSAPR Better-than-BART'' rulemaking. In the August 2018 proposal, EPA proposed to affirm that the weight of evidence supported the conclusion that the Texas SO_2 Trading Program met the requirements of a BART alternative.[86] Informed by comments we received on the August 2018 proposal, we issued a supplemental proposal in November 2019 that proposed to amend a number of provisions of the Texas SO_2 Trading Program, including the addition of an assurance level. EPA's proposed analysis in November of 2019 accompanying those amendments, updates in certain respects and replaces the analysis of the Texas program's stringency for purposes of determining the appropriateness of relying on the CSAPR Better-than-BART findings for the Texas BART-alternative program.

As explained in the November 2019 supplemental proposal and in Section III.A.I above, an assurance level represents the total level of annual emissions above which units participating in the program will be penalized with a higher allowance surrender ratio than the one-to-one ratio that applies to emissions below the assurance level. The assurance level we proposed was determined by relying on the same analysis and methodology that were used to set assurance levels in the original CSAPR rulemaking.[87] Using this methodology, EPA proposed a variability limit for Texas set at 16,688 tons, which is seven percent of the original trading budget of 238,393 tons. We are finalizing the variability limits set at 16,688 tons with no change from proposal and in light of the minor correction to the trading program budget, as discussed in section III.A.1, we are finalizing an assurance level of 255,083 tons rather than the 255,081-ton assurance level we proposed in the November 2019 supplemental proposal. This 255,083-ton assurance level represents the highest annual SO_2 emissions anticipated from units subject to the Texas program.

[79] EPA's determination that Texas' participation in CSAPR for ozone-season NO_X satisfies NO_X BART for EGUs is final and we did not reopen that determination in our August 2018 proposal or our November 2019 supplemental proposal.

[80] See U.S. EPA, Denial of Petition for Partial Reconsideration of ''Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas'' (82 FR 45481; Sept. 29, 2017) (EPA–HQ–OAR–2016–0598). A copy of the denial of petition letter sent to the petitioners and the denial of petition Notice of Availability (NOA) published in the **Federal Register** are available at Docket ID EPA–HQ–OAR–2016–0598.

[81] See U.S. EPA, Denial of Petition for Partial Reconsideration of ''Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas'' (82 FR 45481; Sept. 29, 2017) (EPA–HQ–OAR–2016–0598). A copy of the denial of petition letter sent to the petitioners and the denial of petition Notice of Availability (NOA) published in the **Federal Register** are available at Docket ID EPA–HQ–OAR–2016–0598.

[82] *Id.*

[83] *See* Technical Support Document for Demonstration of the Transport Rule as a BART Alternative, Docket ID No. EPA–HQ–OAR–2011–0729–0014 (December 2011), available in the docket for this action.

[84] *See* Sensitivity Analysis Accounting for Increases in Texas and Georgia Transport Rule State Emissions Budgets, Docket ID No. EPA–HQ–OAR–2011–0729–0323 (May 29, 2012), available in the docket for this action.

[85] 83 FR at 43595.

[86] 83 FR at 43602.

[87] *See* Power Sector Variability Final Rule TSD (July 2011), available at *https://www.epa.gov/csapr/power-sector-variability-final-rule-tsd* and in the docket for this action.

In addition to being consistent with the original CSAPR methodology for setting assurance levels, EPA also believes that an assurance level set at 255,083 tons is appropriate for the Texas SO_2 Trading Program because it will strengthen the stringency of the Texas SO_2 Trading Program in terms of ensuring that annual emissions from participating units will remain below that level. This allows EPA to project with confidence emissions under the Texas SO_2 Trading Program for purposes of determining whether the trading program meets the requirements of a BART alternative.

In the modeling conducted for the proposed CSAPR Better-than-BART determination in 2011, projected SO_2 emissions from Texas' EGUs under CSAPR were 266,600 tons. Subsequent to performance of that modeling, the CSAPR SO_2 budget for Texas was increased by 50,517 tons. In the BART-alternative sensitivity analysis utilized for the final 2012 CSAPR Better-than-BART determination, EPA made the conservative assumption that SO_2 emissions from Texas EGUs under CSAPR could potentially increase by the full amount of the Texas budget increase, or up to 317,100 tons per year (266,600 + 50,517). (While this level of emissions would have exceeded Texas' CSAPR budget, it would not have been in excess of Texas' amended assurance level under the CSAPR program of 347,476 tons. In any case, the figure was solely intended to represent a conservative assumption that all allowances allocated under Texas' amended CSAPR budget would be emitted.) In that BART-alternative sensitivity analysis, EPA demonstrated that CSAPR was expected to provide for greater reasonable progress than BART nationwide even with potential SO_2 emissions from Texas EGUs under CSAPR as high as 317,100 tons.[88] By comparison, the Texas SO_2 Trading Program has a budget of 238,395 SO_2 tons (plus 10,000 tons in the Supplemental Allowance Pool), and we are finalizing an assurance level of 255,083 tons in this final action.

In determining that the Texas program will perform at least as stringently as CSAPR would have, EPA also must account for the emissions from certain EGUs that would have been subject to CSAPR but are not included in the Texas program. Even with these emissions factored in, the Texas program is designed to ensure reductions similar to or greater than CSAPR. In our analysis in this final action, we are finalizing the more conservative emissions assumptions for these units provided in our November 2019 supplemental proposal. In our August 2018 proposal, we had used an assumption that emissions from these units could be as high as 27,500 tons per year.[89] As proposed in our November 2019 supplemental proposal,[90] we are updating our analysis by adjusting this assumption to 35,000 tons per year. Given that Texas units that were in the CSAPR program but not covered by the Texas SO_2 Trading Program had a combined maximum annual emission level of 34,129 tons over the past five years (2014–2018) and considering that several of these units have recently shut down or have been announced for shutdown in the near future,[91] EPA regards this as a conservative assumption for emissions performance from these units. Even when this conservative figure is added to the highest annual SO_2 emissions anticipated from units under the Texas program, 255,083 tons per year (*i.e.,* the assurance level for the program), the total figure is 290,083 tons per year. This figure is still 27,017 tons below the 317,100 ton per year emissions level EPA had used in the CSAPR Better-than-BART analysis.

In addition to finding that the differences in source coverage between the two trading programs do not affect EPA's determination, we also find that the relative stringency of the Texas SO_2 Trading Program as compared to CSAPR is further demonstrated in the following points, as discussed in our August 27, 2018 affirmation proposal:

- This BART alternative includes all BART-eligible coal-fired units in Texas, additional coal-fired EGUs, and some additional BART-eligible gas and gas/fuel oil-fired units.
- Covered sources under the Texas SO_2 Trading Program we are taking final action to affirm represent 89% [92] of all SO_2 emissions from all Texas EGUs in both 2016 and 2017, and approximately 85% of CSAPR allocations for existing units in Texas.
- The remaining 11% (100 minus 89) of 2016 and 2017 emissions from sources not covered by the Texas SO_2 Trading Program come from gas units that rarely burn fuel oil or from coal-fired units that on average are better controlled for SO_2 than the covered sources and generally are less relevant to visibility impairment. As such, any shifting of generation to non-covered sources, as might occur if a covered source were to reduce its operation in order to remain within its SO_2 emissions allowance allocation, would result in fewer emissions to generate the same amount of electricity.
- Furthermore, the non-inclusion of a large number of gas-fired units that rarely burn fuel oil reduces the amount of available allowances for such units that would typically and collectively be expected to use only a fraction of their CSAPR emissions allowances. Many of these sources typically emit at levels much lower than their allocation level.
- The BART alternative does not allow purchasing of allowances from out-of-state sources. Emission projections under CAIR and CSAPR showed that Texas sources were anticipated to purchase allowances from out-of-state sources.[93] [94]

Based on our quantitative and qualitative assessment of the operation of the BART alternative as presented here, we are taking final action to affirm our determination that the Texas SO_2 Trading Program as amended in this final action through the addition of the 255,083-ton assurance level and other amendments discussed in section III.A.1, will result in annual emissions from the covered EGUs and other EGUs in Texas that are lower than what was required under Texas participation in CSAPR's SO_2 trading program. Because this is the case, EPA can rely on the CSAPR Better-than-BART analysis to demonstrate, by the clear weight of the evidence, that the Texas SO_2 Trading Program, in conjunction with continued implementation of CSAPR in other states, provides greater reasonable progress than BART. Accordingly, we are taking final action to affirm that the Texas SO_2 Trading Program, as

[88] 83 FR at 43595.

[89] 83 FR 43602.

[90] 84 FR at 61853.

[91] *See* ''Texas EGU SO_2 emissions, 2014–2018.xlsx'', available in the docket for this action. Sandow Station units 5A and 5B have been permanently retired. AEP has announced retirement of Oklaunion by September 2020. Gibbons Creek is currently not operating although it has not been officially retired.

[92] In 2016, EGUs included in the program emitted 218,292 tons of SO_2, and other EGUs emitted 27,507 tons (11.2% of the total emitted by Texas EGUs). In 2017, sources included in the program emitted 245,871 tons of SO_2, and other EGUs emitted 30,122 (10.9%).

[93] See section 10 of the 2009 Texas Regional Haze SIP. Table 10–7 shows CAIR 2018 emission projections of approximately 350,000 tons SO_2 emitted from Texas EGUs compared to CAIR budget for Texas of 225,000 tons. Thus, Texas was projected to purchase 125,000 tons of allowances (350,000 − 225,000) from out-of-state sources. The SIP submittal can be found in *www.regulations.gov,* docket ID EPA–R06–OAR–2016–0611, document EPA–R06–OAR–2016–0611–0002.

[94] For the projected annual SO_2 emissions from Texas EGUs under CSAPR, see Technical Support Document for Demonstration of the Transport Rule as a BART Alternative, Docket ID No. EPA–HQ–OAR–2011– 0729–0014 (December 2011) (2011 CSAPR/BART Technical Support Document), available in the docket for this action at table 2–4.

amended in today's final action, satisfies the requirements for a BART alternative under 40 CFR 51.308(e)(2)(i)(E).

Section 51.308(e)(2)(iii). This provision requires that the emission reductions from BART alternatives occur ''during the period of the first long-term strategy for regional haze.'' The Texas SO_2 BART alternative was implemented beginning in January 2019, and thus emission reductions needed to comply with the BART alternative were required to take place by the end of 2019. In our August 2018 proposal,[95] we proposed to affirm our determination that for the purpose of evaluating Texas' BART alternative, the end of the period of the first long-term strategy for Texas is 2021, consistent with the requirement that states submit revisions to their long-term strategy to address the second planning period by July 31, 2021.[96] We also proposed to affirm our determination that because the emission reductions from the Texas SO_2 Trading Program will be realized prior to that date, the necessary emission reductions will take place within the period of Texas' first long-term strategy for regional haze. We received a comment raising the concern that this determination we proposed to affirm would be at odds with the national finding in the January 2017 action that our amendments there ''do not affect the development and review of state plans for the first implementation period. . . .'' 82 FR at 3080. After further review of our discussion in the January 2017 final rule making amendments to the Regional Haze Rule and consideration of the comments we received pertaining to this issue, we are not finalizing a position in this action that the first planning period has been extended to July 31, 2021.

Nonetheless, we are finalizing our determination that the Texas SO_2 Trading Program satisfies the timing requirements of 51.308(e)(2)(iii), because the level of emissions achieved by the covered Texas units was below the budget of the Texas program prior to the end of 2018 and the program took effect immediately at the beginning of 2019. This meets the requirement at (e)(2)(iii) that the emission reductions called for by the BART alternative occur before the end of the period for the first long-term strategy. As discussed in our November 2019 supplemental proposal, the combined SO_2 emissions from Texas EGUs participating in the intrastate trading program were 179,630 SO_2 tons in 2018, which is well below the Texas SO_2 Trading Program budget of 238,395 tons (as well as the assurance level of 255,083 tons we are finalizing in this action).[97] Therefore, the emissions reductions secured under the Texas SO_2 Trading Program occurred prior to the end of the period of the first long-term strategy for regional haze. EPA has previously proposed a view that where emission reductions required by a BART alternative are already achieved in practice during the first planning period, even though the enforceable requirement was not mandated until after the planning period, this can satisfy 40 CFR 51.308(e)(2)(iii). This was our position in our action proposing to approve a SIP revision from the State of Arkansas establishing a BART-alternative for the Domtar Ashdown Mill.[98] There, we explained that even though the BART alternative emission limits for the Domtar Ashdown Mill became enforceable by the State on February 28, 2019, the SIP revision submitted by Arkansas provided adequate documentation demonstrating that the two subject-to-BART units at the Domtar Ashdown Mill have actually been operating at emission levels below the BART alternative emission limits since December 2016.[99] Based on the documentation provided in the Arkansas SIP revision, we proposed to find that the subject-to-BART units at the Domtar Ashdown Mill satisfy the timing requirements of 40 CFR 51.308(e) that the necessary emission reductions associated with the BART alternative occur during the first long-term strategy for regional haze.[100] Consistent with that proposed action, we do not interpret § 51.308(e)(2)(iii) as requiring that all enforceable limits on annual emissions under the Texas SO_2 Trading Program be in place by December 31, 2018, or that the Trading Program itself must be implemented by December 31, 2018, if the emission levels called for by the BART alternative are achieved prior to that date and remain at or below that level until the alternative becomes enforceable (which in this case, is immediately following 2018). We are taking final action that the Trading Program satisfies the timing requirements of § 51.308(e)(2)(iii).

Section 51.308(e)(2)(iv). This provision requires a demonstration that the emission reductions resulting from the emissions trading program or other alternative measure will be surplus to those reductions resulting from measures adopted to meet requirements of the CAA as of the baseline date of the SIP. When promulgating this requirement in 1999, the EPA explained that emission reductions must be ''surplus to other Federal requirements as of the baseline date of the SIP, that is, the date of the emission inventories on which the SIP relies.'' [101] The baseline date for the 2009 Texas Regional Haze SIP emission inventory was previously established as 2002 during SIP planning stages for the first implementation period.[102] The emission reductions secured under the Texas SO_2 Trading Program are additional and will not result in double-counting of reductions from other Federal requirements since they will occur after the original 2002 emission inventory. Thus, this BART alternative satisfies the requirements of § 51.308(e)(2)(iv).

Section 51.308(e)(2)(vi). For plans that include an emissions trading program that establishes a cap on total annual emissions of SO_2 or NO_X from sources subject to the program, this provision requires the owners and operators of sources to hold allowances or authorizations to emit equal to emissions, and allows the owners and operators of sources and other entities to purchase, sell, and transfer allowances. The Texas SO_2 Trading Program is modeled after the EPA's CSAPR SO_2 Group 2 Trading Program, and we are taking final action to affirm that the Program satisfies the requirements of 51.308(e)(2)(vi). Similar to the CSAPR SO_2 Group 2 Trading Program, the Texas SO_2 Trading Program sets an SO_2 emission budget for affected units and sources in the State of Texas. Authorizations to emit SO_2, known as allowances, are allocated to affected units. The Texas SO_2 Trading Program provides flexibility to affected units and sources by allowing units and sources to determine their own compliance path; this includes adding or operating control technologies, upgrading or improving controls, switching fuels, and using allowances. Sources can buy and sell allowances and bank (save) allowances for future use so long as each source holds enough allowances to account for its emissions of SO_2 by the allowance transfer deadline shortly after the end of the compliance period.

Section 51.308(e)(2)(vi)(A). This provision requires applicability provisions defining the sources subject to the program. The State (or EPA) must demonstrate that the applicability

[95] 83 FR 43592.

[96] 40 CFR 51.308(f).

[97] 84 FR 61853.

[98] See 85 FR 14847 (March 16, 2020).

[99] 85 FR 14861.

[100] 85 FR 14861.

[101] *See* 64 FR 35714, 35742 (July 1, 1999); *see also* 70 FR 39104, 39143 (July 6, 2005).

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

provisions (including the size criteria for including sources in the program) are designed to prevent any significant potential shifting within the State of production and emissions from sources in the program to sources outside the program. The October 2017 final rule and the August 2018 proposal affirming that rule discuss the provisions of the Texas SO_2 Trading Program that satisfy § 51.308(e)(2)(vi)(A).[103] In this final action, we are making amendments to some of these provisions, as discussed in section III.A.1. We are terminating the opt-in provisions by removing sections 97.904(b), 97.911(b), and 97.921(d) from the regulations, and we are making a minor correction to the Texas SO_2 Trading Program to relabel ''Newman unit 4,'' which is already participating in the Texas SO_2 Trading Program, as its components: ''Newman unit **4'' and ''Newman unit **5.'' We are taking final action to find that with these amendments, the Texas SO_2 Trading Program continues to have applicability provisions that satisfy § 51.308(e)(2)(vi)(A).

Section 51.308(e)(2)(vi)(B). This provision requires allowance provisions ensuring that the total value of allowances (in tons) issued each year under the program will not exceed the emissions cap (in tons) on total annual emissions from the sources in the program. 40 CFR Section 97.921 establishes how the Administrator will record the allowances for the Texas SO_2 Trading Program and ensures that the Administrator will not record more allowances than are available under the program consistent with 40 CFR 51.308(e)(2)(vi)(B).

Sections 51.308(e)(2)(vi)(C)–(E). The provisions of sections 51.308(e)(2)(vi)(C)–(E) require monitoring provisions providing for consistent and accurate measurements of emissions from sources in the program to ensure that each allowance actually represents the same specified tonnage of emissions and that emissions are measured with similar accuracy at all sources in the program; recordkeeping provisions that ensure the enforceability of the emissions monitoring provisions and other program requirements; and reporting provisions requiring timely reporting of monitoring data with sufficient frequency to ensure the enforceability of the emissions monitoring provisions and other program requirements and the ability to audit the program. The monitoring, recordkeeping, and reporting provisions for the Texas SO_2 Trading Program at 40 CFR 97.930–97.935 are consistent with those requirements in the CSAPR SO_2 Group 2 Trading Program. The provisions in 40 CFR 97.930–97.935 require the subject units to comply with the monitoring, recordkeeping, and reporting requirements for SO_2 emissions in 40 CFR part 75, thereby satisfying the requirements of 51.308(e)(2)(vi)(C)–(E).

Section 51.308(e)(2)(vi)(F). This provision requires tracking system provisions which provide for a tracking system that is publicly available in a secure, centralized database to track in a consistent manner all allowances and emissions in the program. The EPA is implementing the Texas SO_2 Trading Program using the Allowance Management System, which provides a consistent approach to implementation and tracking of allowances and emissions for the EPA, subject sources, and the public consistent with the requirements of 40 CFR 51.308(e)(2)(vi)(F).

Section 51.308(e)(2)(vi)(G). This provision requires authorized account representative provisions ensuring that the owners and operators of a source designate one individual who is authorized to represent the owners and operators in all matters pertaining to the trading program. The requirements at 40 CFR 97.913–97.918 for designated and alternate designated representatives are consistent with the requirements of 40 CFR 51.308(e)(2)(vi)(G) and are also consistent with the EPA's other trading programs under 40 CFR part 97.

Section 51.308(e)(2)(vi)(H). This provision requires allowance transfer provisions providing procedures that allow timely transfer and recording of allowances, minimize administrative barriers to the operation of the allowance market, and ensure that such procedures apply uniformly to all sources and other potential participants in the allowance market. Allowance transfer provisions for the Texas SO_2 Trading Program at 40 CFR 97.922 and 97.923 provide procedures that allow timely transfer and recording of allowances; these provisions will minimize administrative barriers to the operation of the allowance market and ensure that such procedures apply uniformly to all sources and other potential participants in the allowance market, consistent with 40 CFR 51.308(e)(2)(vi)(H).

Section 51.308(e)(2)(vi)(I). This provision requires compliance provisions prohibiting a source from emitting a total tonnage of a pollutant that exceeds the tonnage value of its allowance holdings, including the methods and procedures for determining whether emissions exceed allowance holdings. The provision requires that such method and procedures apply consistently from source to source. Compliance provisions for the Texas SO_2 Trading Program at 40 CFR 97.924 prohibit a source from emitting a total tonnage of SO_2 that exceeds the tonnage value of its SO_2 allowance holdings as required by 40 CFR 51.308(e)(2)(vi)(I).

Section 51.308(e)(2)(vi)(J). This provision requires penalty provisions providing for mandatory allowance deductions for excess emissions that apply consistently from source to source. Additionally, the tonnage value of the allowances deducted must equal at least three times the tonnage of the excess emissions. The Texas SO_2 Trading Program includes automatic allowance surrender provisions at 40 CFR 97.924(d) that apply consistently from source to source and the tonnage value of the allowances deducted shall equal at least three times the tonnage of the excess emissions, consistent with the penalty provisions at 40 CFR 51.308(e)(2)(vi)(J).

Section 51.308(e)(2)(vi)(K). For a trading program that allows banking of allowances, this provision requires provisions clarifying any restrictions on the use of these banked allowances. The Texas SO_2 Trading Program provides for banking of allowances under 40 CFR 97.926; Texas SO_2 Trading Program allowances are valid for compliance in the control period of issuance or may be banked for use in future control periods, consistent with 40 CFR 51.308(e)(2)(vi)(K).

Section 51.308(e)(2)(vi)(L). This provision requires program assessment provisions providing for periodic program evaluation to assess whether the program is accomplishing its goals and whether modifications to the program are needed to enhance performance of the program. The CAA and EPA's implementing regulations require comprehensive periodic revisions of implementation plans for regional haze under 40 CFR 51.308(f) and periodic review of the state's regional haze approach under 40 CFR 51.308(g) to evaluate progress towards the reasonable progress goals for Class I areas located within the state and Class I areas located outside the State affected by emissions from within the state. Because the Texas SO_2 Trading Program is a BART-alternative and part of the long-term strategy for Texas' Regional Haze obligations, this program will be reviewed in each comprehensive periodic revision and progress report. We anticipate these revisions and progress reports will provide the information needed to assess program

[103] *See* 82 FR at 48360 and 83 FR at 43602.

performance, as required by 40 CFR 51.308(e)(2)(vi)(L).

Based on the analysis presented here, EPA is taking final action to affirm our determination that the Texas SO_2 Trading Program, as amended in this final action, meets the requirements of 40 CFR 51.308(e)(2) as a BART alternative for SO_2 to satisfy Texas' Regional Haze obligations.

3. PM BART

We are taking final action to affirm our October 2017 approval of the portion of the Texas Regional Haze SIP that determined that PM BART emission limits are not required for any Texas EGUs. The majority of Texas' BART-eligible EGUs rely on BART alternatives for both SO_2 and NO_X emissions (or have otherwise been determined to be not subject to BART). We approved Texas' pollutant-specific screening analysis for PM as appropriate and consistent with a 2006 guidance document in which the EPA stated that pollutant-specific screening can be appropriate where a state is relying on a trading program as a BART alternative to address both NO_X and SO_2 BART.[104] All of the BART-eligible sources participating in the SO_2 intrastate trading program have visibility impacts from PM alone below the subject-to-BART threshold of 0.5 deciviews (dv).[105] [106] Furthermore, the BART-eligible sources not participating in the intrastate trading program were screened out of BART for all visibility impairing pollutants. Therefore, we are finalizing our affirmation of our prior approval that no Texas EGUs are subject to PM BART and that PM BART emission limits are not required for any Texas EGUs under EPA's 2006 guidance.

4. Reasonable Progress

This final action addressing the BART requirements is part of the long-term strategy for Texas and will contribute to making reasonable progress toward the goal of natural visibility conditions at Texas' and downwind Class I areas. However, the EPA is not determining at this time that this final action fully resolves the EPA's outstanding obligations with respect to reasonable progress that resulted from the Fifth Circuit's remand of our reasonable progress FIP.[107] We intend to take a separate, future action to address the Fifth Circuit's remand.

B. Interstate Transport of Pollutants That Affect Visibility

We are taking final action to affirm our finding that Texas' participation in CSAPR to satisfy NO_X BART and our SO_2 intrastate trading program, as amended in today's final action, fully addresses Texas' interstate visibility transport obligations for the following six NAAQS: (1) 1997 8-hour ozone; (2) 1997 $PM_{2.5}$ (annual and 24 hour); (3) 2006 $PM_{2.5}$ (24-hour); (4) 2008 8-hour ozone; (5) 2010 1-hour NO_2; and (6) 2010 1-hour SO_2. The basis for this final action is our determination in the October 2017 FIP that the regional haze measures in place for Texas are adequate to ensure that emissions from the State do not interfere with measures to protect visibility in nearby states, because the emission reductions are consistent with the level of emissions reductions relied upon by other states during interstate consultation under 40 CFR 51.308(d)(3)(i)–(iii) and when setting their reasonable progress goals.[108] As discussed in our August 2018 affirmation proposal, the 2009 Texas Regional Haze SIP relied on participation in CAIR to meet SO_2 and NO_X BART requirements for Texas EGUs. Under CAIR, Texas EGU sources were projected to emit approximately 350,000 tons of SO_2 annually.[109] These are the 2018 EGU emission projections used by CENRAP for Texas that other states potentially impacted by emissions from Texas sources agreed upon during interstate consultation and relied on in their regional haze SIPs. In today's final action, we are finalizing four revisions to strengthen the Texas SO_2 Trading Program and increase its consistency with CSAPR, including the addition of an assurance level consistent with the 2012 CSAPR demonstration. As discussed elsewhere in today's final action, Texas EGU annual SO_2 emissions for sources covered by the trading program will be constrained by the assurance level of 255,083 tons. Including an estimated 35,000 tons per year of emissions from units not covered by the Texas SO_2 Trading Program yields 290,083 tons of SO_2, which is well below the 350,000-ton emissions projection for 2018 for Texas sources under CAIR or the 317,100-ton emissions level assumed for Texas sources under CSAPR participation in the BART-alternative sensitivity analysis utilized for the 2012 CSAPR Better-than-BART determination. Additionally, the October 2017 FIP relies on CSAPR for ozone season NO_X as an alternative to EGU BART for NO_X, which exceeds the NO_X emission reductions that would have been realized from Texas EGUs under CAIR and that other states relied upon during interstate consultation for the first planning period.[110] Because the revisions to the Texas SO_2 Trading Program we are finalizing in today's final action ensure emission reductions consistent with and below the emission levels relied upon by other states during interstate consultation, we find that these revisions provide further support for our earlier finding that the BART alternative in the October 2017 FIP results in emission reductions adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for the six identified NAAQS.

IV. Summary and Responses to Significant Issues Raised by Commenters

We received both written and oral comments at the public hearings we held in Austin and Dallas. We also

[104] *See* discussion in Memorandum from Joseph Paisie to Kay Prince, ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' July 19, 2006.

[105] Our technical evaluation of Texas' PM screening approach in the 2009 Texas Regional Haze SIP submittal was originally presented in a December 16, 2014 proposal. See 79 FR 74817, 74848–49 (Dec. 16, 2014). As noted in our August 2018 proposal, the basis of our affirmation of our approval of Texas' PM screening approach remains consistent with the technical evaluation we provided at the time. See 83 FR 43586, at 43593.

[106] Stryker Creek Unit ST2 is covered by CSAPR for NO_X and by the SO_2 trading program but was not included in the 2009 Regional Haze SIP. In our August 2018 proposal, we explained that based on our own evaluation in the January 2017 proposal and October 2017 final rule, we determined that the visibility impact attributable to PM emissions from Stryker Creek Unit ST2 is a small fraction (roughly 1%) of the 0.786 dv aggregate impact of the unit's emissions from all pollutants. This is well below the subject-to-BART threshold of 0.5 dv. See 83 FR 43586, at 43593.

[107] Order, *Texas* v. *EPA,* 16–60118 (5th Cir. Mar. 22, 2017).

[108] See 2009 Texas Regional Haze SIP, section 4.3 titled ''Consultations On Class I Areas In Other States.'' The submittal can be found at *www.regulations.gov,* Docket ID EPA–R06–OAR–2016–0611, Document ID EPA–R06–OAR–2016–0611–0002.

[109] See section 10 of the 2009 Texas Regional Haze SIP. Table 10–7 shows that under CAIR, the 2018 emission from Texas EGUs were projected to be approximately 350,000 tons SO_2. The SIP submittal can be found in *www.regulations.gov,* Docket ID EPA–R06–OAR–2016–0611, Document ID EPA–R06–OAR–2016–0611–0002.

[110] Under CAIR, Texas had an annual 2009 CAIR Phase 1 budget of 181,017 tons of NO_X and an annual 2015 CAIR Phase 2 budget of 150,845 tons of NO_X. See Section 11, Table 11–15 of the 2009 Texas Regional Haze SIP. The SIP submittal can be found at *www.regulations.gov,* Docket ID EPA–R06–OAR–2016–0611, document ID EPA–R06–OAR–2016–0611–0002. The 2018 EGU emission projections for NO_X used by CENRAP for Texas, which other states potentially impacted by emissions from Texas sources agreed upon during interstate consultation and relied on in their regional haze SIPs, were approximately 160,000 tons. In contrast, under the CSAPR ozone season NO_X trading program, Texas' 2017 NO_X ozone season budget is 52,301 tons of NO_X. See 81 FR 74504, 74508 (Oct. 26, 2016).

received written comments on the August 27, 2018 affirmation proposed action and the November 14, 2019 supplemental proposed action. The full text of comments received is included in the publicly posted docket associated with this action at *www.regulations.gov.* We reviewed all public comments that we received. Below we provide a summary of the most significant comments and our responses. A complete summary of all of the comments we received, and our responses thereto are contained in a separate document titled Response to Comments, which is found in the docket associated with this final action.

A. Texas SO_2 Trading Program as a BART Alternative

Comment: We received one comment asserting that in promulgating the Texas SO_2 Trading Program as a BART alternative in our October 2017 FIP and in affirming the trading program in our August 2018 proposal, EPA did not properly demonstrate that the trading program meets the requirements for an alternative to BART for SO_2 because EPA did not compare the alternative to source-specific BART in Texas. The commenter asserted that the Regional Haze Rule at 40 CFR 51.308(e)(2) specifies that BART and associated emission reductions achievable for each source within the State subject to BART and covered by the alternative program must be evaluated first for the purpose of comparing to the BART alternative and determining whether the alternative makes greater reasonable progress than BART. The commenter also noted that the Regional Haze Rule at § 51.308(e)(2)(i)(C) provides that the only exception to this requirement is when the emissions trading program or other alternative measure has been designed to meet a requirement other than BART and that in such cases, EPA may analyze BART for similar types of sources within a source category instead of on a source-specific basis. The commenter asserted that in promulgating the Texas SO_2 Trading Program, EPA did not properly demonstrate that the trading program is better than BART and meets the requirements for an alternative to BART because EPA has not determined which units are subject to BART, and did not provide an analysis of BART at each source subject to BART and covered by the trading program to compare against the trading program. According to the commenter, even if presumptive BART levels were an appropriate assumption that is not outdated, EPA would still be required to compare the trading program directly to presumptive BART, which it has not done. The commenter also contended that EPA's approach of comparing the intrastate trading program to Texas' participation in the SO_2 trading program under CSAPR is not appropriate because EPA withdrew Texas from the CSAPR program for SO_2 and thus CSAPR cannot lawfully be BART for SO_2 for Texas EGUs.

The commenter also disagreed with EPA's position that the trading program was designed to meet requirements other than BART, namely the interstate transport requirements and the long-term strategy provisions. The commenter asserted that even if the trading program had indeed been designed to meet requirements other than BART, this would still not authorize EPA to completely forego analyzing BART for the sources subject to BART and covered by the trading program.

Response: As explained in our August 27, 2018 proposal, in addition to being a sufficient alternative to BART, the trading program is designed to secure reductions consistent with visibility transport requirements.[111] As allowed by the requirements for a BART alternative in § 51.308(e)(2)(i)(C), we are exercising the exception allowed when the alternative measure ''has been designed to meet a requirement other than BART (such as the core requirement to have a long-term strategy to achieve the reasonable progress goals established by States).'' See 40 CFR 51.308(e)(2)(i)(C). In such circumstances, BART and associated emission reductions may be analyzed for similar sources ''based on both source-specific and category-wide information, as appropriate.'' When promulgating the 2012 CSAPR Better-than-BART rule, the EPA relied on an analysis of BART in CSAPR states and a demonstration showing that CSAPR would result in greater reasonable progress than BART under the test in 40 CFR 51.308(e)(3). In that analysis, EPA utilized simplified assumptions regarding ''presumptive'' BART limits at BART-eligible sources. This analysis was conducted on a category-wide basis (all fossil fuel-fired EGUs). See 77 FR 33642, 33649–50 (June 7, 2012). This analysis satisfied 51.308(e)(2)(i)(C) because CSAPR was designed to meet the requirements of CAA section 110(a)(2)(D)(i)(I) (sometimes referred to as ''good neighbor'' obligations) for certain NAAQS pollutants. EPA finds that reliance on the category-wide BART analysis from the 2012 CSAPR Better-than-BART demonstration is appropriate here, because, although the Texas program is not designed to meet good neighbor obligations under section 110(a)(2)(D)(i)(I), it is designed to meet separate CAA requirements for interstate visibility transport, as explained in section III.B above. This satisfies the condition in 51.308(e)(2)(i)(C) for using category-wide information such as presumptive BART limits in analyzing the Texas SO_2 Trading Program. Thus, the BART determinations derived from that CSAPR Better-than-BART demonstration are an appropriate BART benchmark for comparison against the Texas SO_2 Trading Program given that the Texas SO_2 Trading Program is modeled on the CSAPR trading programs. In this action, we are relying, in part, on that same 2012 CSAPR Better-than-BART demonstration to show that the clear weight of evidence demonstrates that the Texas SO_2 Trading Program, which is modeled on the CSAPR trading programs, will provide for greater reasonable progress than BART in Texas. Indeed, the anticipated maximum potential SO_2 emissions in Texas under the Texas SO_2 Trading Program BART alternative are less than the SO_2 emission levels from Texas EGUs that were forecast in the demonstration for Texas EGU emissions assuming their participation in the CSAPR SO_2 trading program. Under CSAPR, the total allocations for all existing EGUs in Texas were 279,740 SO_2 tons, the total state budget including the amounts of allowances set aside for potential allocation to new units was 294,471 tons, and the assurance level was 347,476 tons. The level of emissions assumed for Texas EGUs in the BART alternative sensitivity analysis utilized for the 2012 CSAPR Better-than-BART determination is 317,100 SO_2 tons.[112] By comparison, the Texas SO_2 Trading Program has a budget of 238,395 SO_2 tons, and we are finalizing an assurance level of 255,083 tons in this action. In light of the three-

[111] 83 FR 43586, at 43597.

[112] For the projected annual SO_2 emissions from Texas EGUs, *see* Technical Support Document for Demonstration of the Transport Rule as a BART Alternative, Docket ID No. EPA–HQ–OAR–2011–0729–0014 (December 2011) (2011 CSAPR/BART Technical Support Document at Table 2–4,), available in the docket for this action. Certain CSAPR budgets were increased after promulgation of the CSAPR final rule (and the increases were addressed in the 2012 CSAPR/BART sensitivity analysis memo. See memo entitled ''Sensitivity Analysis Accounting for Increases in Texas and Georgia Transport Rule State Emissions Budgets,'' Docket ID No. EPA–HQ–OAR–2011–0729–0323 (May 29, 2012), available in the docket for this action. The increase in the Texas SO_2 budget was 50,517 tons which, when added to the Texas SO_2 emissions projected in the CSAPR + BART-elsewhere scenario of 266,600 tons, yields total potential SO_2 emissions from Texas EGUs of approximately 317,100 tons.

for-one penalty surrender ratio imposed on emissions exceeding the 255,083-ton assurance level, the assurance level represents the highest annual SO_2 emissions anticipated from units subject to the Texas program. In reality, in light of ongoing changes in the electric-generating sector in Texas, there is a reasonable expectation that actual emissions under the Texas program would remain well below the assurance level. We are also finalizing a more conservative (*i.e.,* higher) estimate of 35,000 annual SO_2 tons as the projected emissions from Texas units that would have been in the CSAPR program but are not in the Texas SO_2 Trading Program. This more conservative estimate is based on these units' maximum annual emission level of 34,129 tons over the past five years (2014–2018) and taking into consideration that several of these units have recently shut down or have been announced for shutdown in the near future.[113] Adding that amount to the Texas SO_2 Trading Program's assurance level of 255,083 tons yields 290,083 tons. Assuming this figure represents a firm upper bound on annual SO_2 emissions from the relevant EGUs in Texas under the Texas SO_2 Trading Program, this is less than the 317,100-ton figure EPA had demonstrated was acceptable in the original 2012 CSAPR Better-than-BART analysis.

Comment: The commenter asserted that it was not appropriate for EPA to conclude that because CSAPR achieves greater reasonable progress than BART when averaged across all affected states that this necessarily means that CSAPR achieves greater reasonable progress than BART in Texas. The commenter asserted that the legal test that EPA used during the original ''CSAPR Better-than-BART'' rulemaking is fundamentally different than the test EPA must use in assessing whether the Texas SO_2 Trading Program is better than BART. The commenter asserted that in making its determination that CSAPR achieves greater reasonable progress than BART under 40 CFR 51.308(e)(3), EPA was required to demonstrate that visibility does not decline in any Class I area and that there is an overall improvement in visibility, determined by *comparing the average differences* between BART and the alternative over all affected Class I areas. The commenter argued that since EPA averaged the visibility improvement from CSAPR over all the affected Class I areas in the eastern half of the country in the CSAPR Better-than-BART determination, Texas was able to take advantage of reductions from other states without having to reduce its SO_2 emissions as much as it would have had to do under source-by-source BART. The commenter argued that in contrast to the CSAPR Better-than-BART determination, the legal test required under §§ 51.308(e)(2)(i) and 51.308(e)(3) to demonstrate that the Texas SO_2 Trading Program is better than BART cannot rest on improvements from CSAPR in other states. The commenter argued that EPA must instead demonstrate that the Texas SO_2 Trading Program is better than BART in Texas alone by examining the visibility improvement at only the Class I areas affected by Texas sources.

Response: We disagree that EPA must demonstrate that the Texas SO_2 Trading Program is better than BART by examining visibility improvement at only Class I areas in Texas and Class I areas in other states affected by Texas sources. As explained in our proposal affirming the Texas SO_2 Trading Program, the 2012 demonstration that CSAPR, as finalized and amended in 2011 and 2012, meets the Regional Haze Rule's criteria for a demonstration of greater reasonable progress than BART is also the primary evidence that the Texas trading program achieves greater reasonable progress than BART.[114] In the 2012 CSAPR Better-than-BART rule, the EPA relied on an analytic demonstration that included an air quality modeling study showing that CSAPR results in greater improvements in average visibility across all affected Class I areas as compared to adopting source-specific BART. Our finding with respect to the Texas program relies on the demonstration underlying our CSAPR Better-than-BART Rule and our 2017 CSAPR Better-than-BART affirmation (including the basis for our denial of a petition for reconsideration in the latter,[115] as discussed in section I.D of the preamble). Thus, we find that given the particular circumstances in this case, we are not required to focus only on Class I areas in Texas and Class I areas in other states affected by Texas sources. Rather, we are assessing the Texas program in the context of the larger CSAPR Better-than-BART analysis. We find that due to the specific circumstances in this case, as described above, it is reasonable and appropriate to consider improvements in average visibility across all affected Class I areas in our assessment of the Texas SO_2 Trading Program to demonstrate that it is better than BART. The amendments to the Texas SO_2 Trading Program we are finalizing in this action ensure that EGU emissions under the Texas program will remain well below the amount assumed in the BART-alternative sensitivity analysis utilized for the 2012 CSAPR Better-than-BART determination (*i.e.,* 317,100 tons), and thus visibility levels at Class I areas impacted by sources in Texas are anticipated to be at least as good as (and likely better than) the levels projected under Texas participation in the larger CSAPR SO_2 trading program.

Comment: We received one comment that asserted that EPA's reliance on CSAPR to design the Texas SO_2 Trading Program as a BART alternative is not appropriate because in doing so, EPA did not account for new circumstances or update emissions and other data, which the commenter claimed EPA typically does when evaluating BART. The commenter asserted that if EPA had taken the same technical approach it has taken in other regional haze actions of using the most up-to-date data, this would have changed the allowance distribution of the Texas SO_2 Trading Program. For instance, the commenter argued that in developing the Texas SO_2 Trading Program, EPA should have taken into account the retirements of Welsh 2, Big Brown Units 1 and 2, Monticello Units 1, 2, and 3, and Sandow 4 and 5. Similarly, the commenter asserted the Texas SO_2 Trading Program should have included rule provisions for properly dealing with the impending retirement of the two JT Deely units instead of the current method of addressing retired allowances, which the commenter claimed provides no incentive to reduce SO_2 emissions. Additionally, the commenter noted that EPA assigned allocations under CSAPR on the basis of a unit's heat input from 2006–2010 and its emissions from 2003–2010 utilizing a detailed ten-step approach based on the heat input and emissions from those periods. The commenter claimed that EPA should have re-applied the same allocation methodology it used for CSAPR using updated information, and that if EPA had done so, the allocations in many instances would have changed significantly. In support of this argument, the commenter performed this analysis using the same number of years as in the original CSAPR methodology but shifted the year ranges forward to include updated information.

[113] 84 FR 61853.

[114] 83 FR 43586, at 43599.

[115] See U.S. EPA, Denial of Petition for Partial Reconsideration of ''Interstate Transport of Fine Particulate Matter: Revision of Federal Implementation Plan Requirements for Texas'' (82 FR 45481; Sept. 29, 2017) (EPA–HQ–OAR–2016–0598). A copy of the denial of petition letter sent to the petitioners and the denial of petition Notice of Availability (NOA) published in the **Federal Register** are available at Docket ID EPA–HQ–OAR–2016–0598.

The commenter asserted that two cases were analyzed. In the first case, the commenter did not remove retired units and used the original CSAPR methodology to revise the CSAPR allocations while using updated data. In this case, because none of the retired units were removed, the total allocations remained at 238,393 tons. However, the commenter asserted that because the emissions and heat inputs changed with the updated data, almost every unit's allocations changed, in some cases by more than 3,000 tons. In the second case, the commenter asserted that retired units were removed, but the JT Deely units were retained. The commenter asserted that because of the removal of retired units and because of the updated emissions and heat inputs, almost every unit's allocations changed, resulting in a reduction of allocations from 238,393 tons to 176,332 tons. The commenter noted that these additional 62,061 tons in unit allocations that resulted from EPA not using the most updated data in the allocation methodology and not removing retired units should not be moved into the Supplemental Allowance Pool as Section 97.911(a)(2) of the Texas SO_2 Trading Program provides. The commenter argued that these allowances should never have been in the allowance pool in the first place. The commenter concluded that the analysis performed by the commenter demonstrates that if EPA had updated the emissions data and heat input data using the original CSAPR methodology and removed the retired units' allocations, the Texas SO_2 Trading Program would not include excess allowances, which the commenter claimed disincentivizes SO_2 emissions reductions.

Response: As stated in responses to several other comments in this final action and in our Response to Comments document found in the docket for this action, we disagree that in developing a specific trading program, EPA must incorporate new design features, particularly when other legal and policy considerations weigh in favor of making the program similar in design to a specific previous program that does not include those design features. Likewise, EPA is not required to incorporate new design features that may be suggested by a commenter and is not required to update every data element used in the rulemaking. In this instance, the Texas SO_2 Trading Program was designed to qualify as a BART alternative in light of EPA's previous determinations regarding permissible BART alternatives, and for that reason was designed to be as similar as possible to the CSAPR SO_2 program. Both the amounts of the initial allocations to units under the Texas SO_2 Trading Program and the treatment of the allocations to units that have been retired for at least five years are directly based on the analogous provisions in the CSAPR SO_2 program. As discussed in response to another comment on the Texas SO_2 Trading Program's Supplemental Allowance Pool, in those aspects of the overall allocation methodology where the Texas SO_2 Trading Program allowance allocation provisions deviate from the CSAPR SO_2 program allowance allocation provisions, the Texas SO_2 Trading Program is generally more, not less, stringent.

With respect to the commenter's point that the amount of the CSAPR SO_2 program budget for Texas was initially determined based on our assessments of the state's interstate transport obligations at the time of the CSAPR rulemaking, we agree with the statement but do not consider the point relevant to this final action. The origins of the CSAPR budgets are immaterial to this action. Along with certain budget adjustments that were addressed through sensitivity analyses, the CSAPR budgets were used in our 2012 CSAPR Better-than-BART determination and therefore remain relevant for purposes of our determination in this action that the Texas SO_2 Trading Program qualifies as a BART alternative in the context of the 2012 CSAPR Better-than-BART determination.

With respect to the commenter's identification of alternative possible distributions of allowances among the units covered by the program, we do not believe that altering the distribution of allowances while leaving the total number of allowances the same would change the stringency of the program, although it could address concerns regarding whether the distribution among the sources is equitable. As none of the sources covered by the program have raised equity concerns about the initial allocations, and given that we do not understand the commenter to be raising such concerns, we see no reason to redistribute the initial allocations. We address the comments regarding the stringency of the program cap elsewhere.

With regard to the commenter's position that allowances allocated to units that retire should be eliminated from the budget instead of being reallocated, that is of course an option in designing a trading program, but it is not a requirement, and it is not a feature of the CSAPR SO_2 program on which the Texas SO_2 Trading Program was modeled. We were not required and did not find it necessary to take such an approach in the Texas SO_2 Trading Program in order to ensure that the program qualifies as a BART alternative in the context of the 2012 and 2017 CSAPR Better-than-BART determinations.

Comment: We received comments from the State and affected sources in support of our affirmation that the October 2017 Regional Haze FIP satisfies Texas' obligations for BART and in support of our determination that the intrastate SO_2 trading program for certain EGUs in Texas is an appropriate BART alternative and satisfies all SO_2 BART requirements. Several affected sources also provided comments in support of the October 2017 SO_2 trading program over the adoption of a source-by-source approach to address the BART requirements for units subject to BART in Texas. One affected source asserted that the trading program will allow operational flexibility in complying with BART obligations and another affected source asserted that it is appropriate for EPA to respect Texas' preference to meet BART compliance through a BART alternative rather than source-specific BART.

Response: We appreciate the commenter's support of our FIP that establishes an intrastate trading program that caps emissions of SO_2 from certain EGUs in Texas and includes the determination that this program meets the requirements for an alternative to BART for SO_2.

Comment: We received one comment that argued that EPA's reliance on the CSAPR Better-than-BART demonstration is based on the false premise that the Texas SO_2 Trading Program is functionally equivalent to CSAPR. The commenter asserted that the Texas SO_2 Trading Program is not sufficiently similar to CSAPR for a comparison between Texas' overall emissions under the Texas SO_2 Trading Program versus CSAPR to suffice for a weight of evidence determination. In support of the claim that the Texas SO_2 Trading Program and CSAPR are not sufficiently similar, the commenter pointed to the exclusion from the Texas SO_2 Trading Program of a number of Texas EGUs that were covered under CSAPR and argued that EPA presented no real analysis of the visibility impacts of these excluded units. The commenter asserted that for some of these excluded units that have existing scrubbers or other types of SO_2 control, such as Oklaunion, W.A. Parish 8, Oak Grove Units 1 and 2, Twin Oaks Units 1 and 2, and Sandy Creek, EPA should have

evaluated possible upgrades to existing SO_2 controls.

The commenter also argued that there are flaws in how EPA performed its Q/d analysis that constitute arbitrary deviations from EPA's Q/d testing methodology in past regional haze actions and claimed that the deviations were made in order to exclude certain units from the Texas SO_2 Trading Program. For instance, the commenter asserted that EPA's decision to base the Q/d analysis on 2009 emissions was arbitrary and claimed that no rationale was provided for selecting that year of data other than EPA noting that it already had this emissions data available from a previous analysis. The commenter asserted that in contrast to the Q/d analysis EPA used to identify sources to include in the Texas SO_2 Trading Program, in past regional haze actions, EPA has typically considered a 3–5 year range of data to account for data variability from year to year. The commenter also asserted that the Twin Oaks facility had a Q/d greater than EPA's stated threshold of 10 but it was nonetheless excluded on the basis that EPA estimated that the Q/d of each of its individual units were likely less than 10. The commenter claimed that EPA's decision to deviate from its approach is arbitrary and was made in order to exclude the Twin Oaks facility from the trading program. Similarly, the commenter asserted that EPA's decision to exclude Oklaunion from the trading program even though its Q/d was 85, which is much higher than the EPA's stated threshold of 10, is arbitrary. The commenter asserted that EPA's decision to exclude units that came online after 2009 on the basis that these units would be permitted and constructed using emission control technology determined under either BACT or LAER review, was inappropriate given that EPA made no comparison between the levels of control under BACT or LAER versus BART for these units. The commenter argued that this comparison was necessary given that, according to the commenter, BART has been demonstrably more stringent than either BACT or LAER. The commenter also asserted that the opt-in provision is yet another feature of the Texas SO_2 Trading Program that makes the trading program not functionally equivalent to CSAPR, as EPA removed the opt-in provision in CSAPR.

Response: We continue to believe that the Texas SO_2 Trading Program will achieve SO_2 emission levels that are functionally equivalent to those that had been previously projected for Texas' participation in the original CSAPR program and that our reliance on the original CSAPR Better-than-BART determination for the clear weight of evidence demonstration required under § 51.308(e)(2)(i)(E) was thus appropriate in this case. What we mean by the phrase ''functionally equivalent'' is that while the two programs are not identical, the differences between the Texas SO_2 Trading Program and CSAPR are either not significant or work to demonstrate the relatively greater stringency of the Texas SO_2 Trading Program as compared to CSAPR. As the commenter notes, in our August 27, 2018 proposal affirming the Texas SO_2 Trading Program, we listed several points that help demonstrate the relative stringency of the Texas SO_2 Trading Program as compared to CSAPR.[116] These points are summarized below:

- Covered sources under the Texas SO_2 Trading Program represent approximately 85% of CSAPR allocations for existing units in Texas. Covered sources under the Texas SO_2 Trading Program represent 89% of all SO_2 emissions from all Texas EGUs in both 2016 and 2017.
- The remaining 11% of 2016 and 2017 emissions from Texas EGUs not covered by the BART alternative come from gas units that rarely burn fuel oil or from coal-fired units that on average are better controlled for SO_2 than the covered sources and generally are less relevant to visibility impairment.[117] As a result, any shifting of generation to non-covered sources, as might occur if a covered source were to reduce its operation in order to remain within its SO_2 emissions allowance allocation, is expected to result in fewer emissions to generate the same amount of electricity.
- We also noted that the non-inclusion of a large number of gas-fired units that rarely burn fuel oil reduces the amount of available allowances for such units that would typically and collectively be expected to use only a fraction of their CSAPR allowance allocations. Many of these sources typically emit at levels much lower than their allocation level.
- Emissions projections under CAIR and CSAPR showed that Texas sources were anticipated to purchase allowances from out-of-state sources. In contrast to CSAPR, the Texas SO_2 Trading Program does not allow purchasing of allowances from out-of-state sources. This will ensure that emissions reductions resulting from implementation of the Texas SO_2 Trading Program will take place in Texas instead of a neighboring state. In this respect, implementation of the Texas SO_2 Trading Program can be expected to result in greater visibility benefits at Texas Class I areas than CSAPR.

Furthermore, in the final analysis for this action, we have updated our emissions assumptions to be even more conservative (*i.e.,* we assume the potential for higher emissions) for units that were in the CSAPR program but not covered by the Texas SO_2 Trading Program. In the August 2018 proposal, we had used an assumption that emissions from these units could be as high as 27,500 tons per year.[118] However, in the updated analysis presented for comment in the November 2019 SNPRM, we adjusted this assumption to 35,000 tons per year. This number reflects emissions for the past five years (2014–2018), which EPA regards as a conservative assumption for emissions performance from these units. Even when this conservative figure is added to the highest annual emissions anticipated from units under the Texas program, 255,083 tons per year (*i.e.,* the assurance level for the program), the total figure is 290,083 tons per year. As EPA explains in section III.A.2 of the preamble for this action, that figure is still 27,019 tons below the 317,100 ton per year emissions level for Texas that EPA assumed in the BART-alternative sensitivity analysis utilized for the 2012 CSAPR Better-than BART determination.

Based on the above points and the fact that the combination of (1) the source coverage for the Texas SO_2 Trading Program, (2) the total allocations for EGUs covered by the program, and (3) recent and foreseeable emissions trends from those EGUs both covered and not covered by the program will result in future EGU emissions in Texas that are less than the SO_2 emission levels forecast in the 2012 Better-than-BART demonstration for Texas EGU emissions assuming CSAPR participation,[119] it is not reasonable to expect that the Texas SO_2 Trading Program would result in less visibility benefit in Texas Class I areas compared to Texas' participation in CSAPR. Thus, we continue to believe that we have sufficiently demonstrated that differences in source coverage between the Texas SO_2 Trading Program as amended in this final action and CSAPR are either not significant or work to demonstrate the relative stringency of the Texas SO_2 Trading Program as compared to CSAPR.

Our decision to exclude from the Texas SO_2 Trading Program certain units that were covered under CSAPR was not arbitrary as the commenter

[116] 83 FR 43586, at 43591.

[117] *Id.*

[118] 83 FR 43586, at 43602.

[119] 83 FR 43586, at 43591.

contends, but rather was generally based on both the results of a Q/d analysis as well as the units' potential to impact visibility at Class I areas based on our consideration of certain circumstances specific to each unit. Based on our consideration of the above, we found it appropriate to exclude certain units that were previously covered under CSAPR from the Texas SO_2 Trading Program. For example, some units are already operating SO_2 controls and we thus do not consider the potential visibility impacts from these units to be significant relative to those coal-fired EGUs participating in the program, and we therefore excluded them from the Texas SO_2 Trading Program. In some cases, relatively new units that began operation after 2009 and have been permitted and constructed using emission control technology determined under either Best Available Control Technology (BACT) or Lowest Achievable Emission Rate (LAER) review, as applicable. As we explained in our proposal affirming the Texas SO_2 Trading Program, because these newer units are already operating BACT or LAER controls, we do not consider the potential visibility impacts from these units to be significant relative to those coal-fired EGUs participating in the program. The commenter contends that in these cases, we should have compared the levels of control under BACT or LAER versus BART for these units because BART can in some cases be more stringent than either BACT or LAER. However, given the much greater anticipated visibility impact from uncontrolled coal-fired EGUs participating in the program, we continue to believe that it is reasonable for us to focus our efforts on these uncontrolled coal-fired EGUs while excluding the newer, already controlled EGUs from the Texas SO_2 Trading Program.

The commenter specifically identifies Oklaunion, W.A. Parish Unit 8, Oak Grove Units 1 and 2, Sandy Creek Unit 1, and the Twin Oaks facility as units that were covered under CSAPR, but which were excluded from the Texas SO_2 Trading Program. Although Oklaunion has a Q/d greater than 10, we ultimately excluded Oklaunion from the Texas SO_2 Trading Program based on our consideration that the facility consists of one coal-fired unit that is not BART-eligible; annual emissions of SO_2 in 2016 from this source were 1,530 tons, which is less than 1% of the total annual emissions for EGUs in the state; and annual SO_2 emissions were only 933 tons in 2017. In short, the most recent emissions from this facility are small relative to other non-BART units included in the program.[120] And as noted in our November 2019 supplemental proposal, American Electric Power announced in 2018 its plans to shut down the Oklaunion Power Plant by September 2020.[121] With regard to W.A. Parish Unit 8, this unit is not BART-eligible, but is co-located with BART-eligible units. Although we decided to include most coal-fired units that are not BART-eligible but are co-located with BART-eligible EGUs in the Texas SO_2 Trading Program to prevent any significant shifting of generation and SO_2 emissions from participating sources to non-participating sources within the same facility, we decided not to include W.A. Parish Unit 8 because this unit has a scrubber installed that maintains an SO_2 emission rate four to five times lower than the emission rate of the other coal-fired units at the facility that are uncontrolled and are participating in the Texas SO_2 Trading Program (Parish Units 5, 6, and 7).[122] Therefore, we expect that any shifting of generation from the participating units at the Parish facility to Parish Unit 8 would not present a problem, and instead would result in a decrease in overall emissions from the source. Similarly, with regard to Oak Grove Units 1 and 2, and Sandy Creek Unit 1, these are relatively newer coal fired units that began operation in late 2009 or after, are not BART eligible and have scrubbers installed that maintain SO_2 emission rates much lower than the uncontrolled units included in the program.[123] Thus, we did not include Oak Grove Units 1 and 2, and Sandy Creek Unit 1 for participation in the Texas SO_2 Trading Program. Although the Twin Oaks facility was identified as having a Q/d greater than 10, we did not include it in the trading program based on its relatively low potential to impact visibility at Class I areas. For instance, the facility does not include any BART-eligible EGUs; the Q/d for this facility is 14.2, which is significantly lower than that of other Texas facilities on our list with a Q/d value over 10;[124] and the estimated Q/d for each individual unit (Units 1 and 2) is less than 10. Considering the above, we do not consider the potential visibility impacts from Twin Oaks Units 1 and 2 to be significant relative to the other coal-fired EGUs in Texas with Q/d's much greater than 10 and therefore did not include them in the program.[125] We also note that annual SO_2 emissions from Twin Oaks Units 1 and 2 in 2017–2019, which are the three most recent years for which annual emissions data are available, have been well below the 2009 emissions level of 4,707 tons of SO_2.[126] Thus, we believe the results of the Q/d analysis as well as our consideration of unique circumstances specific to each unit are sufficient information to justify excluding certain units from the Texas SO_2 Trading Program that were included under CSAPR, without necessitating a quantitative examination of the visibility impact of excluding these units.

With regard to the comment contending that we arbitrarily selected 2009 as the emissions year in our Q/d analysis, we note that to identify facilities that may impact visibility at Class I areas in our October 2017 final rule, we relied on an already existing Q/d analysis that we prepared as part of the December 2014 proposal to address Texas' reasonable progress requirements, and which was based on 2009 emissions.[127] In that proposed action, we also reviewed 2010 and 2011 emission data that became available as we were developing that proposed rule. We determined that the only EGU facility that was above the Q/d for 2010 and 2011 compared to the 2009 analysis was the Oak Grove facility, which came online in late 2009. As we discuss above, this is a new facility that is equipped with scrubbers and we determined it was not necessary to include them in the Trading Program. The Regional Haze Rule does not require us to select a range of years for the emissions data for our Q/d analysis

[120] 83 FR 43597.

[121] See 84 FR at 61853, footnote 20.

[122] 83 FR 43596.

[123] *Id.* 43601.

[124] *Id.* FR 43596–97. As discussed in our August 2018 proposal, after identifying the BART-eligible sources included in the Texas SO_2 Trading Program, we evaluated additional sources for potential inclusion in the trading program based on their potential to impact visibility at Class I areas. We used a Q/d value of 10 as a threshold for identification of facilities that may impact visibility at Class I areas and could be included in the trading program. We identified a total of 17 facilities in Texas with Q/d values greater than 10, some of which are not BART-eligible and had not already been identified for inclusion in the program. The Q/d values for these 17 facilities range from 14.2 (for Twin Oaks) to 425.4 (for Monticello).

[125] *Id.* FR 43597.

[126] Annual SO_2 emissions from Twin Oaks Units 1 and 2 were 2,472 tons in 2017; 2,523 tons in 2018; and 2,408 tons in 2019. See excel spreadsheet ''Twin Oaks- SO_2 annual emissions_2009 and 2017–2019.xlsx,'' available in the docket for this action.

[127] See the TX RH FIP TSD that accompanied our December 2014 proposal to address reasonable progress requirements for Texas (79 FR 74818 (Dec 16, 2014)), and the Excel file ''2009statesum_Q_D.xlsx.'' These files are available in Docket ID EPA–R06–OAR–2014–0754, see Document ID EPA–R06–OAR–2014–0754–0007 and EPA–R06–OAR–2014–0754–0007–05.

nor does it identify a particular year that must be used for the emissions data. We have the discretion to select the emissions data year as long as we provide a reasonable justification for our selection, as we have done in this case.[128]

With regard to the comment regarding the opt-in provision, we appreciate the commenter's input on whether that provision differs from the provisions of the CSAPR SO_2 program in a manner that could decrease the relative overall stringency of the Texas SO_2 Trading Program. In our November 2019 supplemental proposal, we proposed to modify the regulations to terminate the opt-in provision, and we are adopting that proposed modification in this final action.

Comment: One commenter asserted that the Texas SO_2 Trading Program is arbitrary, capricious, and unlawful because EPA did not follow its own policies and regulations in the ''clear weight of evidence'' approach taken under § 51.308(e)(2)(i)(E) to demonstrate that the trading program achieves greater reasonable progress than BART. The commenter pointed to EPA's action on the Utah Regional Haze SIP, in which EPA stated that pursuant to the Regional Haze Rule requirements for a BART alternative, the clear weight-of-evidence test requires three steps that can generally be summarized as follows: (1) Use information and data that can inform the decision . . . ; (2) Evaluate the information and recognize the relative strengths and weaknesses of the metrics used, including assigning weights to each piece of information that indicate the degree to which it supports a finding that the alternative program will achieve greater visibility benefits; and (3) Collectively consider the weights assigned to the individual pieces of information and consider the total weight of all the information to determine whether the proposed BART alternative will clearly provide for greater reasonable progress than BART at the impacted Class I areas. The commenter asserted that in contrast to our evaluation of Utah's BART alternative, EPA did not follow the three-step process for making a clear weight of the evidence demonstration under 40 CFR 51.308(e)(2) to demonstrate that the Texas SO_2 Trading Program achieves greater reasonable progress than BART. The commenter asserted that EPA should have identified, weighed and carefully considered certain information the commenter considers to be relevant and easily available to inform EPA's clear weight of evidence approach and decision regarding the Texas SO_2 Trading Program, including EPA's January 2017 Texas BART proposal, recent emissions data, presumptive BART emission rates and emission reductions, the weaknesses of the outdated CSAPR evaluations, significant differences between the Texas SO_2 Trading Program and CSAPR, and EPA's own previous evaluation when withdrawing Texas from CSAPR showing greater emission reductions under BART.

The commenter further asserted that the clear weight of evidence demonstrates that the trading program will not make greater reasonable progress than BART based on EPA's prior determination that CSAPR would achieve lower emissions reductions than source-specific BART for Texas EGUs. The commenter cited to three prior rulemakings in which, according to the commenter, the EPA has concluded that CSAPR would achieve less reasonable progress than source-specific BART in Texas: (1) The January 2017 BART proposal; (2) the original CSAPR Better-than-BART rulemaking; and (3) the 2017 rulemaking to remove Texas from CSAPR's SO_2 trading program. The commenter asserted that since the Texas SO_2 Trading Program is intended to mimic the effect of CSAPR, and CSAPR would achieve less reasonable progress than BART in Texas, it follows that the Texas SO_2 Trading Program would also achieve less reasonable progress than BART, and therefore would not satisfy the requirements of the Regional Haze Rule at 40 CFR 51.308(e)(2), (e)(2)(i)(E), and (e)(3).

Response: EPA disagrees that we are applying a different standard for ''clear weight of evidence'' than we have in other cases. The specific circumstances of Texas as compared to Utah are readily distinguishable. Specifically, the Better-than-BART demonstration for our Texas SO_2 Trading Program relies on the quantitative modeling, analyses and demonstrations supporting our June 2012 ''CSAPR Better-than-BART'' determination and September 2017 ''CSAPR Better-than-BART affirmation finding'' (as recently reaffirmed by our denial of a petition for reconsideration on the latter). This analysis follows the two-part quantitative test of § 51.308(e)(3), and in our weight of evidence approach, we rely on that technical analysis, as supplemented by additional evidence that the Texas intrastate trading program achieves at least the same amount of emission reductions as were projected for Texas in the CSAPR analysis (including accounting for potential shifting in emissions to CSAPR states with the removal of Texas from the program). The commenter attempts to elevate EPA's general guidance on conducting a clear weight of evidence analysis, set forth in a separate regional action, into a mandatory test that states or the agency must always adhere to. However, the evidence-based inquiry called for under § 51.308(e)(2)(i)(E) is inherently fact-specific, and EPA has set forth why information in this record supports its findings. The State of Utah, in a far different context, had attempted to show by a series of metrics (many of which were novel and unique to that SIP submittal) that a BART alternative achieved greater reasonable progress than BART, but the state failed to explain how it weighed these metrics, and EPA found that one of the most important metrics in that instance (visibility impact on the 98th percentile day) did not actually support the alternative.[129] Here, rather than setting out a list of factors to evaluate, EPA is primarily relying on the CSAPR Better-than-BART analysis under the quantitative test of § 51.308(e)(3) (in addition to showing that other § 51.308(e)(2) requirements are met), as explained elsewhere in the record.

Comment: One commenter asserted that the Texas SO_2 Trading Program is not an adequate SO_2 BART alternative because it is not a cap and trade program that might actually reduce SO_2 emissions beyond the overall cap. Further, the commenter argues that the cap set by EPA in the trading program is too high and actually allows the participating units to increase their SO_2 emissions. The commenter stated that in upholding EPA's authority to select an alternative to source-specific BART, the D.C. Circuit has held that the overriding requirement for each regional haze plan is that it make reasonable progress toward eliminating haze pollution. The commenter asserted that the Texas SO_2 Trading Program does not satisfy this overriding requirement since, according to the commenter, it would not result in any progress because it does not require any emissions reductions relative to actual emissions from covered sources in 2015, 2016, and 2017. The commenter argued that the Texas SO_2 Trading Program actually authorizes covered sources to increase emissions relative to actual emissions in 2015, 2016, and 2017, and that it therefore does not achieve greater reasonable progress than source-specific BART and is not an appropriate BART alternative. The commenter also claimed that by

[128] 83 FR 43597.

[129] 81 FR at 43898.

authorizing even higher emissions than seen in 2015–2017, the Texas SO_2 Trading Program would likely further erode whatever gains were made post-2014. The commenter asserted that the Texas SO_2 Trading Program authorizes sources to emit as much as 293,104 SO_2 tons considering that the Supplemental Allowance Pool may grow over time, which would equate to a 47,234 ton increase over 2017 emissions, and a 74,813 ton increase over 2016 emissions. The commenter argued that even if the potential growth in the Supplemental Allowance Pool (from an initial 10,000 tons to 54,711 tons) is ignored, and one uses 248,393 tons as the total number of allowances, the Texas SO_2 Trading Program would still authorize an increase in emissions over actual emissions in 2015, 2016, and 2017. The commenter asserted that the Texas SO_2 Trading Program would thus fail to require greater reasonable progress than BART and would actually authorize greater pollution than the status quo. Furthermore, the commenter asserted that source-specific BART is the only option EPA has proposed that is consistent with statutory requirements and goals. According to the commenter, the January 2017 source-specific BART proposal, or even presumptive BART, would reduce emissions and improve visibility far more than the Texas SO_2 Trading Program, and should be finalized in place of the trading program.

Additionally, the commenter argued that in EPA's determination that the Texas SO_2 Trading Program will decrease SO_2 emissions relative to 2014 emission levels, EPA's selection of 2014 as the baseline year for determining whether the Texas SO_2 Trading Program would reduce emissions and improve visibility was arbitrary. The commenter asserted that EPA should have instead selected 2017 as the baseline year because that is the most recent year for which annual emissions data is available and in which Texas sources were not part of CSAPR for SO_2. The commenter claimed that the Texas SO_2 Trading Program will result in no progress toward the goal of eliminating haze pollution and will therefore be in direct violation of the Clean Air Act's visibility mandate.

Response: We do not agree that addressing Texas' SO_2 BART requirements through a source-specific BART FIP is the only option that meets the regulatory and statutory requirements. Our October 2017 final rule fulfilled our mandatory duty to address the BART requirements for Texas EGUs through the promulgation of a FIP containing a BART alternative in the form of an intrastate trading program. The Texas SO_2 Trading Program, as amended in this final action through the addition of the 255,083-ton assurance level and other amendments discussed in section III.A.1 of this final action, will result in annual emissions from the covered EGUs and other EGUs in Texas that are lower than what was required under Texas participation in CSAPR's SO_2 trading program. Thus, the clear weight of evidence is that, overall, the Texas trading program (considered in the larger context of CSAPR) will provide greater reasonable progress than BART at the covered sources and satisfies the requirements for a BART alternative under 40 CFR 51.308(e)(2)(i)(E).

The comment contending that we arbitrarily elected not to use 2017 as the baseline emissions year for comparing the Texas SO_2 Trading Program to BART is incorrect. We considered 2014 as the appropriate most recent year for comparing the Texas SO_2 Trading Program to BART for the purposes of meeting the requirement of 40 CFR 51.308(e)(2)(i)(D) given that Texas sources were subject to the CSAPR SO_2 trading program in 2015 and 2016 but are no longer subject to that program.[130] This analysis was included in our October 2017 final rule, at a time when 2017 emissions data were not yet available. The Regional Haze Rule does not require us to select 2017 or any specific year as the baseline year for our assessment under 40 CFR 51.308(e)(2)(i)(D) of emission reductions achievable by the trading program, and commenter establishes no basis why we should have been required to update this analysis in our August 2018 proposal to affirm the rule. Our BART alternative analysis for Texas relied on 2014 data to be consistent with the CSAPR Better-than-BART analysis given that we are relying on the demonstration in the 2012 CSAPR Better-than-BART rule (as affirmed in 2017) to show that the clear weight of evidence demonstrates that the Texas SO_2 Trading Program, which is modeled on the CSAPR trading programs, will provide for greater reasonable progress than BART in Texas as required under 40 CFR 51.308(e)(2)(i)(E).[131] We have provided a reasonable explanation for our selection of 2014 as the historical baseline year for the purposes of meeting the requirement of 40 CFR 51.308(e)(2)(i)(D).

The commenter's suggestion that the Texas SO_2 Trading Program should be structured to achieve additional emission reductions beyond the cap is effectively similar to other comments advocating for a lower cap or a more stringent program generally. As discussed elsewhere in this document, we continue to believe that the Texas SO_2 Trading Program is sufficiently stringent to meet the requirements to qualify as a BART alternative in the context of the 2012 CSAPR Better-than-BART rule and the 2017 CSAPR Better-than-BART affirmation finding. The comment contending that the Texas SO_2 Trading Program authorizes sources to increase emissions relative to actual emissions in 2015, 2016, and 2017, and authorizes greater pollution than the status quo mischaracterizes the Texas SO_2 Trading Program and reflects a misunderstanding of its purpose. First, we note that the Texas SO_2 Trading Program will achieve an average reduction of at least 54,213 tons per year over the 2014 emissions, which is the difference between the aggregate 2014 SO_2 emissions of the covered Texas EGUs (309,296 tons per year)[132] and the assurance level of 255,083 tons we are finalizing in this action. The assurance level represents the highest annual SO_2 emissions anticipated from units subject to the Texas SO_2 Trading Program in light of the three-for-one penalty surrender ratio imposed on emissions exceeding that level, and is therefore a conservatively high figure to compare against 2014 actual emissions levels. Second, and notwithstanding our position that we appropriately selected 2014 as the baseline year for the purpose of this analysis, we note that even if we had selected 2017 as the baseline year, we disagree that the Texas SO_2 Trading Program would authorize greater pollution than the status quo given that the trading program now contains an assurance level limiting SO_2 emissions from Texas EGUs participating in the trading program where no prior SO_2 emission limits under the regional haze program existed for these sources. Therefore, we disagree that the Texas SO_2 Trading Program authorizes greater pollution than the status quo even under the assumption of 2017 as the baseline year for comparison against the Texas SO_2 Trading Program as the status quo ''authorizes'' much higher emissions (due to there being no enforceable program at all and the only limitations being the facilities' current permit limits), even if actual emissions

[130] 83 FR 43598.

[131] Note that the year 2014 is not relevant to the question of whether emissions achieved by the program are surplus to the baseline date for purposes of 40 CFR 51.308(e)(2)(iv). For purposes of meeting the requirements of 40 CFR 51.308(e)(2)(iv), the baseline date is 2000–2004.

[132] 84 FR at 61854.

happened to be below that level. As discussed in section III.A.2 of this final action, we note that the Texas SO_2 Trading Program with the added assurance level we are finalizing in this action, also achieves significantly lower emissions relative to the year 2002.[133] These emission reductions that are secured by the Trading Program contribute to improvements in visibility from the baseline period for the first planning period and are permanent and enforceable as part of the long-term strategy for the State of Texas.

Further, the purpose of the program is not to achieve some particular quantum, much less a maximum quantum, of emission reductions as compared to some reference point for ''current'' emission levels. In fact, whether the Texas SO_2 Trading Program allows for a potential increase in emissions from recent or current emission levels is not the relevant question under the BART alternative provisions of the Regional Haze Rule. In order to satisfy the BART alternative test of 40 CFR 51.308(e)(2)(i)(E), the alternative must, on the clear weight of evidence, achieve greater reasonable progress in visibility improvements than would be achieved through the installation and operation of BART at the covered sources. This test calls for a comparison in stringency between two regulatory regimes, BART and the BART alternative. The Texas SO_2 Trading Program is modeled on and set at a stringency level comparable to CSAPR in Texas, such that the CSAPR Better-than-BART analysis may be relied upon in determining the adequacy of this program. As discussed in section III.A.2, we find that we have satisfied the BART alternative test of 40 CFR 51.308(e)(2)(i)(E). Whether actual emissions may increase or decrease from some particular historical level under the program is immaterial so long as emissions remain below the level requisite to make the ''greater reasonable progress'' showing.

To the extent the commenter is asserting that certain aspects of the program, such as allocations to retired units, the availability of banking, and allocations from the Supplemental Allowance Pool, pose a risk that the program will fail to achieve the emission levels assumed in our analysis, this theoretical concern is addressed by amendments to the program finalized in this action. To address concerns regarding potentially higher SO_2 emissions in individual years from Texas EGUs participating in the trading program, on November 1, 2019, we signed a supplemental notice of proposed rulemaking that proposed to add assurance provisions to the Texas SO_2 Trading Program. Under the assurance provisions, if the total emissions of the sources in the program in any year exceed the annual program budget by more than a variability limit of 16,688 tons, the emissions over that ''assurance level'' will trigger a requirement for some sources to surrender three allowances for each ton of emissions, providing a strong disincentive against emissions exceeding the assurance level. We are finalizing that supplemental proposal in this action.[134] As we explained in the supplemental proposal, the assurance level effectively moots any concerns regarding annual emission performance under the program by establishing a cap implemented via the penalty surrender ratio. This is because when a mass-based trading program includes a ''cap'' on overall annual emissions, as the Texas SO_2 Trading Program now does with the addition of the assurance provisions, that overall ''cap'' on emissions set by the program (here, the assurance level) effectively determines the stringency of the program in each year. With the addition of an assurance level, the potential risk of an undue relaxation of the annual stringency in the program is minimized given that sources will remain strongly incentivized to keep annual emissions below the level at which the three-for-one surrender penalty is imposed. Thus, how allowances are allocated or banked within that cap does not affect the overall stringency of the program.[135]

Comment: The commenter asserted that even a ''successful'' cap and trade program cannot avoid localized impacts to particular Class I Areas, much less to local communities most impacted by large pollution sources, and that the Trading Program is therefore not an adequate BART alternative.

Response: The Regional Haze Rule does not require that a BART alternative achieve greater visibility improvements than BART at each particular Class I area, and only requires that a BART alternative does not result in declines in visibility compared to the baseline in any class I area. EPA's decision to authorize alternative measures, including emissions trading programs, subject to those requirements, in the original 1999 Regional Haze Rule is beyond the scope of this action. Further, the test EPA devised under 51.308(e)(3) for evaluating whether a BART alternative makes greater reasonable progress calls for an evaluation of whether there could be unacceptable localized visibility impacts under a BART alternative. In particular, the analysis asks whether visibility will decline in any class I area under the BART alternative as compared with the baseline scenario. This evaluation was done as part of the 2012 CSAPR Better-than-BART analytic demonstration, which was relied upon in developing the Texas SO_2 Trading Program. That analysis showed no decline in visibility in any Class I area compared to the baseline emissions scenario.

B. PM BART

Comment: We received one comment raising several objections to EPA's proposal to affirm approval of Texas' finding that no PM BART controls are necessary for EGUs based on Texas' pollutant-specific screening analysis for PM. The commenter asserted that the Regional Haze Rule and the BART Guidelines require that the BART screening analysis evaluate the impacts of all pollutants together, not just PM, and that a source-specific, five-factor analysis of PM BART must then be conducted for each EGU found to be subject to BART. The commenter asserted that Texas' pollutant-specific screening analysis did not meet these requirements and that EPA's proposed approval of Texas' finding that its sources are exempt from PM BART is thus inappropriate. The commenter also argued that EPA's proposal to affirm approval of Texas' pollutant-specific screening analysis for PM BART is arbitrary and capricious for several reasons, including the following: (1) Approval of Texas' screening approach is contrary to the plain language of the Clean Air Act; (2) Texas' screening approach is directly contrary to the agency's regional haze regulations and mandatory BART guidelines; (3) EPA's approval of a pollutant-specific screening approach arbitrarily departs from the agency's past practice; and (4) EPA failed to provide a rational explanation for proposing to approve Texas' application of a pollutant-specific screening analysis in this case.

Specifically, the commenter claimed that approval of Texas' screening approach is contrary to the plain language of the Clean Air Act because

[133] The Regional Haze Rule provides that the baseline period for the first planning period is 2000–2004. *See* 40 CFR 51.308(d)(2)(i).

[134] The final ''assurance level'' is 255,083 tons, which is the sum of the revised annual program budget of 238,395 tons plus the variability limit of 16,688 tons. As discussed in section III.A.1 of the preamble for this action, for consistency with the assurance provisions, EPA is also making revisions to the Supplemental Allowance Pool provisions that will limit the combined total quantity of allowances issued in any year from the program budget and the Supplemental Allowance Pool to this same level of 255,083 tons.

[135] *See* 84 FR 61854.

the commenter believes this effectively exempts sources from installing PM BART controls without going through the statutory exemption process Congress prescribed. The commenter asserted that Congress specifically provided that sources could be exempted from the BART requirements only if the Administrator determines that a *source* does not or will not, by itself or in combination with other sources, emit any air pollutant which may reasonably be anticipated to cause or contribute to a significant impairment of visibility in any Class I area, and that the FLMs must concur with any proposed exemption. The commenter argued that EPA has not demonstrated that any of the BART-eligible Texas EGUs meet the statutory requirements for an exemption and EPA has not obtained the concurrence of federal land managers for exempting sources for PM BART.

The commenter asserted that Texas' screening approach is directly contrary to the agency's regional haze regulations and mandatory BART guidelines. The commenter asserted that the Regional Haze Rule and BART guidelines do not provide for any exemptions from a five-factor BART analysis for specific pollutant, with the exception of a de minimis exemption under § 308(e)(1)(ii)(C) for sources that emit less than 15 tons per year of particulate matter. The commenter argued that neither EPA nor Texas attempted to demonstrate that this de minimis exemption applies to any of Texas' EGUs.

The commenter also argued that EPA's approval of a pollutant-specific screening approach arbitrarily departs from the agency's past practice. Specifically, the commenter claimed that EPA has rejected similar pollutant-specific approaches to BART determinations in past regional haze actions. For instance, the commenter asserted that in a prior regional haze action where EPA partially disapproved the Arizona Regional Haze SIP (78 FR 46142 (July 30, 2013)), EPA stated that under the Regional Haze Rule, the determination of whether a source causes or contributes to visibility impairment is *not* made on a pollutant-by-pollutant basis and that once a source is determined to be subject to BART, the Regional Haze Rule allows for the exemption of specific pollutants from a BART analysis only if they are below specified de minimis levels.

The commenter also raised an objection to EPA's reliance on a 2006 guidance document in proposing to approve Texas' application of a pollutant-specific screening analysis for PM BART. The commenter argued that the EPA's 2006 guidance document on which EPA based its proposed approval of Texas' pollutant-specific screening analysis was never subject to notice and comment and is therefore not binding. Furthermore, the commenter asserted that EPA did not explain how the 2006 guidance document is applicable in this case given that the guidance document does not contain an analysis or rationale and does not cite or incorporate any technical justification for allowing the use of a pollutant-specific screening approach. The commenter also argued that the guidance document contemplates the use of a pollutant-specific screening analysis in situations where a state is subject to both SO_2 and NO_X emission reductions under the Clean Air Interstate Rule, not CSAPR or some other trading program as in this case. The commenter also argued that reliance on the 2006 guidance document is not appropriate in this case because Texas participates in CSAPR for ozone season NO_X and is therefore not subject to annual NO_X emission limits.

The commenter also asserted that in its screening analysis, Texas did not provide a rationale or justification for its selection of 0.5 dv as the threshold for contribution to visibility impairment. The commenter argued that EPA's BART Guidelines do not authorize states or EPA automatically to use a 0.5 dv contribution threshold, but instead provide that any threshold states use for determining whether a source contributes to visibility impairment should not be higher than 0.5 dv. The commenter claimed that given the number of Texas sources and the magnitude of their impact at affected Class I areas, a contribution threshold lower than 0.5 dv may be appropriate.

Response: We are affirming our approval of Texas' pollutant-specific PM screening analysis and determination that PM BART emission limits are not required for any Texas EGUs as in accordance with EPA guidance and the Regional Haze Rule. As we explained in our August 27, 2018 affirmation proposal, in a 2006 EPA memorandum titled ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' EPA stated that pollutant-specific screening can be appropriate where a state is relying on a trading program as a BART alternative to address both NO_X and SO_2 BART.[136] As discussed in the 2006 guidance, for EGU sources that are addressing the NO_X and SO_2 BART requirements by participation in a trading program as a BART alternative, such as CAIR, the state must still determine whether its BART-eligible EGUs are subject to review under BART for PM. In this situation, as this is the only determination that remains and because the task of predicting the impacts of PM on visibility is a relatively straight-forward exercise, unlike predicting the impacts of the non-linear reacting pollutants SO_2 and NO_X, a pollutant-specific basis to model only the impact of PM emissions on visibility is recommended to determine whether a source is subject to BART for PM. We note that the 2006 memorandum is consistent with the BART Guidelines, which provide that a state ''may choose to perform an initial examination to determine whether a particular BART-eligible source or group of sources causes or contributes to visibility impairment in nearby Class I areas. If your analysis, or information submitted by the sources, shows that an individual source or group of sources (or certain pollutants from those sources) is not reasonably anticipated to cause or contribute to any visibility impairment in a Class I area, then you do not need to make BART determinations for that source or group of sources (or for certain pollutants from those sources).'' [137] In sum, the 2006 EPA memorandum is consistent with the BART Guidelines and clearly states that a pollutant-specific analysis for PM emissions is an appropriate approach in certain carefully circumscribed circumstances, such as are present here.

While the commenter is correct that in our January 4, 2017 BART FIP proposal,[138] we initially proposed to disapprove Texas' technical evaluation and determination in the 2009 Regional Haze SIP that PM BART emission limits are not required for any of Texas' EGUs, this was because Texas was not participating in CSAPR for SO_2 or in any other SO_2 emissions trading program or BART alternative at the time and thus did not meet the criteria described in our 2006 guidance. In our October 2017 final action, we addressed the SO_2 BART requirements for Texas EGUs under a BART alternative consisting of an intrastate trading program. Given that Texas is relying on participation in the CSAPR ozone season trading program for NO_X to

[136] *See* discussion in Memorandum from Joseph Paisie to Kay Prince, ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' July 19, 2006. While the memorandum specifies that pollutant-specific screening is appropriate for states relying on CAIR, it is reasonable to infer that other trading programs, such as CSAPR and the Texas SO_2 Trading Program, also qualify to use this approach.

[137] 40 CFR part 51 Appendix Y, Section III.

[138] 82 FR 912.

satisfy NO_X BART for Texas EGUs and is now also subject to a BART alternative consisting of an SO_2 intrastate trading program to satisfy the SO_2 BART requirements for Texas EGUs, Texas is relying on a trading program as a BART alternative to address both NO_X and SO_2 BART. Thus, pollutant-specific screening for PM as performed by Texas in its 2009 SIP submittal was appropriate, consistent with the BART Guidelines [139] and the 2006 EPA memorandum.[140]

We disagree with the commenter's assertion that EPA's approval of a pollutant-specific screening approach arbitrarily departs from the agency's past practice. EPA has previously determined that this approach is appropriate for EGUs where a State relied on CAIR or CSAPR to satisfy the BART requirements for SO_2 and NO_X and has approved SIPs where the State required its BART-eligible EGUs to only evaluate PM emissions for determining whether they are subject to BART, and, if applicable, for performing a BART control assessment. We also note that in these analyses EPA approved a threshold of 0.5 dv for determining which sources were subject to BART.[141]

With regard to the commenter's assertion that our approval of Texas' selection of 0.5 dv as the threshold for visibility impairment for PM was improper, as an initial matter, as explained in our August 2018 proposal to affirm the October 2017 final rule promulgating the Texas SO_2 Trading Program, we did not reopen the subject-to-BART determinations for sources not covered by the trading program, which screened out of the BART program based on consideration of all visibility pollutants.[142] With respect to the BART sources included in the trading program, EPA requested comment on its PM-specific screening analysis.[143] EPA's basis for approving the 0.5 dv value for screening purposes was that EPA's BART Guidelines allow states conducting source-by-source BART determinations to exempt sources with visibility impacts as high as 0.5 dv.[144] [145] Further, the BART Guidelines provide that in setting a contribution threshold, states should ''consider the number of emissions sources affecting the Class I areas at issue and the magnitude of the individual sources' impacts.'' States have the discretion within the Clean Air Act, Regional Haze Rule, and BART Guidelines to set an appropriate contribution threshold and are free to use a threshold lower than 0.5 dv if they conclude that the location of a large number of BART-eligible sources in proximity of a Class I area justifies this approach. Texas did not determine in its 2009 Regional Haze SIP that there were circumstances in this case to justify the selection of a lower threshold. EPA continues to find that Texas was within its discretion to select a threshold of 0.5 dv in its BART screening analysis. In light of the above-referenced 2006 memorandum recognizing the availability of a pollutant-specific approach to BART where BART sources are already separately controlled for SO_2 and NO_X by one or more BART alternative trading programs, we are finalizing our proposed affirmation that no BART-eligible source in Texas is subject to BART for PM on a pollutant-specific basis. In finalizing an affirmation of our approval of Texas' determinations regarding PM BART, we offer one additional note. We originally proposed to approve Texas' screening approach in 2014,[146] and our October 2017 final action again relied on our technical evaluation in that proposal for the basis of our approval. We therefore incorporate by reference the technical evaluation regarding this issue from our 2014 proposal into the record for this action.[147]

Comment: We received a comment asserting that the 2006 intra-agency memorandum on which EPA relies to propose approval of Texas' pollutant-specific screening approach is inconsistent with the Clean Air Act and the Regional Haze Rule, and EPA's interpretation of its regulations is therefore not entitled to deference. *Bowles* v. *Seminole Rock & Sand Co.,* 325 U.S. 410, 414 (1945) (agency interpretation of its regulation is not controlling where ''it is plainly erroneous or inconsistent with the regulation''); *see also Auer* v. *Robbins,* 519 U.S. 452, 461 (1997) (same). The commenter further asserted that courts have repeatedly criticized agency use of guidance documents in the form of interpretive rules and policy statements to reinterpret regulations, recognizing the potential problem that ''[l]aw is made, without notice and comment, without public participation, and without publication in the **Federal Register** or the Code of Federal Regulations.'' *Decker* v. *Northwest Envtl. Def. Ctr.,* 133 S. Ct. 1326, 1341 (2013); *Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1213–14 (Mar. 9, 2015); *see also Appalachian Power Co.* v. *EPA,* 208 F.3d 1015, 1020 (D.C. Cir. 2000) (criticizing agency use of guidance documents in the form of interpretive rules and policy statements, recognizing the potential problem that ''[l]aw is made, without notice and comment, without public participation, and without publication in the **Federal Register** or the Code of Federal Regulations.'').

Response: EPA has the authority to develop and implement policies and guidance. EPA sometimes issues policy or guidance to encourage compliance with environmental requirements. Policy documents may represent EPA's official interpretation or view of specific issues. However, ultimately, EPA's actions with regards to guidance documents must be consistent with applicable statutory and regulatory requirements. The EPA disagrees that its reference to the 2006 guidance is inconsistent with the CAA or constitutes a legislative or interpretive rule, and we have reasonably relied, in part, on this guidance document in our approval of Texas' determination that no BART-eligible sources in Texas are subject to BART for PM on a pollutant-specific basis. As explained in response to similar comments above, application of pollutant-specific screening for PM is appropriate in Texas and is not inconsistent or at odds with either the CAA statute or applicable EPA regulations, for the reasons explained in response to those comments. We, therefore, disagree that our interpretation of the 2006 memorandum here is inconsistent with the Clean Air Act regarding a pollutant-specific screening approach for PM BART.

C. Appropriateness of the Texas SO_2 Trading Program vs. Source-Specific BART FIP

Comment: One commenter raised objections to EPA's finalization of the October 17, 2017 final rule promulgating the Texas SO_2 Trading Program, asserting that EPA provided no rational basis for finalizing a FIP promulgating an intrastate trading program in place of the source-specific BART FIP proposal that was proposed by EPA in January 2017. The commenter asserted that the January 2017 BART FIP proposal was supported by detailed, source-specific analyses of the cost of

[139] 40 CFR part 51 Appendix Y, Section III.

[140] *See* Memorandum from Joseph Paisie to Kay Prince, ''Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations,'' July 19, 2006.

[141] See for example the approval of Regional haze SIPs for Georgia (77 FR 11452 for proposed rule and 77 FR 38501 for final rule), South Carolina (77 FR 11894 for proposed rule and 77 FR 38509 for final rule), and Kentucky (76 FR 78194 for proposed rule and 77 FR 19098 for final rule).

[142] 83 FR 43598 n. 80.

[143] *Id.* 43592–93.

[144] 70 FR 39104, 39161 (July 6, 2005) and 40 CFR part 51 Appendix Y, Section III.A.1.

[145] 82 FR at 48346 and 79 FR at 74848.

[146] *See* 79 FR 74817, 74848 (Dec. 16, 2014).

[147] 79 FR 74817, 74848.

SO_2 controls, the level of control achievable by different technologies, estimated emissions reductions, and projected visibility improvement from operation of such controls, and that this administrative record demonstrated that the 2017 BART FIP proposal meets the requirements of the Regional Haze Rule and CAA and should have been finalized by EPA.

Response: While EPA proposed source-specific BART emission limits in the January 2017 proposal, under the notice and comment rulemaking process, EPA may decline to finalize a proposed rule or may finalize a rule with changes from proposal based on consideration of additional information received during the comment period. Additionally, EPA may also propose a rule and rationale that differs from its original proposal and does not have an obligation to finalize the initial proposed rule as is the case here. We also note that the Regional Haze Rule does not require source-specific BART determinations, as the regulations at 40 CFR 51.308(e)(2)–(5) allow states, or EPA if promulgating a FIP, to adopt a BART alternative in place of source-specific BART provided that all applicable regulatory requirements related to the BART alternative are satisfied. EPA's obligations are to promulgate a final rule that meets the requirements of the CAA and the Regional Haze Rule, consider and respond to all relevant comments to the final rule, and provide a record of decision-making for its action that is not arbitrary and capricious. In this case, informed by comments we received during the public comment period for the January 2017 proposal from the Texas Commission on Environmental Quality (TCEQ), the Public Utility Commission of Texas (PUC), Luminant, and American Electric Power (AEP), urging us to consider as a BART alternative the concept of emission caps using CSAPR allocations,[148] and based on our independent determination that a BART alternative approach under 40 CFR 51.308(e)(2) would meet all statutory and regulatory requirements and thus be viable for Texas, we did not finalize the source-specific BART emission limits we had proposed and instead we addressed the SO_2 BART requirement for Texas EGUs under a BART alternative consisting of an intrastate trading program in our October 2017 final rule. Having made the determination (in part through reliance on the analysis of CSAPR as a BART alternative as explained elsewhere in the record) that the BART-alternative program satisfies 40 CFR 51.308(e)(2) under the clear weight of evidence test of 40 CFR 51.308(e)(2)(i)(E), EPA need not further explain or justify the program based on a comparison of emission reductions, costs, or visibility improvements that may have been potentially achieved had EPA finalized the source-specific controls we proposed in January 2017. The statute and applicable regulations do not mandate that states, or EPA when it is promulgating a FIP, reach a particular conclusion or outcome regarding cost-effectiveness or emission reductions when applying the five-factor BART analysis, or in designing a BART-alternative program under 40 CFR 51.308(e).

Comment: We received one comment asserting that EPA never identified any errors in the January 2017 BART FIP proposal and that EPA never responded to certain comments submitted on that proposal. The commenter claimed that EPA did not demonstrate that the intrastate trading program would achieve greater reasonable progress than the January 2017 source-specific BART proposal to justify finalizing the intrastate trading program in place of the source-specific BART FIP and that EPA cannot ignore the findings it previously made in the January 2017 BART FIP proposal.

Response: Under the notice and comment rulemaking process, EPA may decline to finalize a proposed rule or may finalize a rule with changes from the proposal based on consideration of additional information received during the comment period. As a general matter, EPA may publish a new proposed rule that supersedes a previously proposed rule in order to take into account newly available information or changes in circumstances that would affect the outcome of the final rule, with no obligation to finalize the originally proposed rule. EPA's obligations are to promulgate a final rule that meets the requirements of the Clean Air Act and the Regional Haze Rule, consider and respond to all relevant comments that are germane to the final rule, and provide a record of decision-making for its action that is not arbitrary and capricious. In this case, informed by comments we received during the public comment period for the January 2017 proposal, and based on our independent determination that this BART alternative approach under 40 CFR 51.308(e)(2) would meet all regulatory requirements and thus be a viable approach for Texas, we addressed the SO_2 BART requirement for Texas EGUs under a BART alternative consisting of an intrastate trading program in our October 2017 final rule instead of finalizing the source-specific BART emission limits we had proposed. In the October 2017 final rule, EPA considered and responded to all comments germane to the final rule and provided a record of decision-making for the final action. We note that some of the comments we received on the January 2017 proposal raised specific issues related to the analyses for the source-specific BART emission limits we proposed, and those comments were no longer relevant once we determined not to promulgate the proposed source-specific BART emission limits in our final action. Therefore, a response to those comments was unnecessary. While in this case, EPA did not publish a new proposal before issuing the October 2017 final rule, we explained the basis for our finalization of the BART alternative in that final action, and we subsequently published a proposal in August 2018 to affirm our October 2017 final rule and solicited comment on important aspects of the rule, as discussed in section II.A of this final action. Informed by comments we received on the August 2018 proposed rule, we issued a supplemental proposal that proposed changes to the Texas SO_2 Trading Program, as discussed in section II.B of this final action. Having made the determination in the October 2017 final action, as further affirmed in today's final action, that the BART-alternative program, as amended in this final action, satisfies 40 CFR 51.308(e)(2) under the clear weight of evidence test of 40 CFR 51.308(e)(2)(i)(E), EPA need not further explain or justify the Texas SO_2 Trading Program based on a comparison of emission reductions, costs, or visibility improvements that may have been potentially achieved had EPA finalized the source-specific controls we proposed in January 2017. Further, in response to the statement contending that EPA cannot ignore the findings it previously made in the January 2017 proposed rule, we note that those proposed source-specific BART analyses and control determinations do not constitute final findings or final Agency action, as they were proposed by EPA but not finalized.

Comment: We received one comment asserting that the only justification EPA provided for finalizing the intrastate trading program in place of the source-specific BART FIP is that the state made this request during the public comment period for the January 2017 BART FIP proposal, and that this justification is inappropriate. The commenter claimed that while the CAA does establish a

[148] 82 FR 48324 at 48327.

cooperative state-federal framework, this does not justify EPA deferring to a State's expressed preferences without providing a valid justification.

Response: This comment mischaracterizes the basis for our finalization of the Texas SO_2 Trading Program in place of source-specific BART controls in the October 2017 final action. While we did explain in the October 2017 final action that we received comments during the public comment period for the January 2017 proposal from the Texas Commission on Environmental Quality (TCEQ), the Public Utility Commission of Texas (PUC), Luminant, and American Electric Power (AEP), urging us to consider as a BART alternative, the concept of emission caps using CSAPR allocations,[149] this was not the sole basis for our finalization of the Texas SO_2 Trading Program in place of source-specific BART controls. Our October 2017 final action promulgating the Texas SO_2 Trading Program was informed by comments we received during the public comment period for the January 2017 proposal, and was based on our independent determination that a BART-alternative approach under 40 CFR 51.308(e)(2) meets all statutory and regulatory requirements and is thus an appropriate approach for addressing the SO_2 BART requirement for Texas EGUs. In addition to meeting all Clean Air Act and Regional Haze Rule requirements, we also explained in the October 2017 final action that the Texas SO_2 Trading Program would result in lower costs and added flexibility for affected sources compared to source-specific SO_2 BART controls.

D. Statutory Requirements for FIP Promulgation and Implementation

Comment: We received one comment asserting that the FIP promulgating the Texas SO_2 Trading Program is arbitrary, capricious, and unlawful because it allows EPA to suspend key provisions of the intrastate trading program if Texas submits a SIP revision, without the need for EPA to approve the SIP before those key provisions of the trading program are suspended. Specifically, the commenter referred to a provision of the Texas SO_2 Trading Program that provides that the ''Administrator may delay recordation of Texas SO_2 Trading Program allowances for the specified control periods if the State of Texas submits a SIP revision before the recordation deadline.'' 40 CFR 97.921(a). Similarly, the trading program includes a provision that provides that the ''Administrator may delay recordation of the Texas SO_2 Trading Program allowances for the applicable control periods if the State of Texas submits a SIP revision by May 1 of the year of the applicable recordation deadline under this paragraph.'' *Id.* § 97.921(b). The commenter claimed that these provisions at 40 CFR 97.921(a) and (b) are arbitrary and capricious and otherwise unlawful because they are counter to the CAA's rulemaking requirements given that no provision of the CAA allows the submission of a SIP to suspend implementation of a FIP. The commenter also asserted that these provisions of the trading program violate the CAA and the Regional Haze Rule because suspension of the trading program would mean that there is no functioning BART alternative in place in the interim period between state submission of the SIP and EPA approval of that SIP. Furthermore, the commenter expressed concern that the Texas SO_2 Trading Program does not include any provision that would resume the intrastate trading program if the submitted SIP was subsequently found to be deficient.

Response: After considering this comment, we proposed in our November 2019 supplemental proposal to modify the Texas SO_2 Trading Program recordation provisions at 40 CFR 97.921 to make clear that submission of a SIP revision by the state does not cause any change in implementation of those provisions unless and until the SIP revision is approved by EPA. We are adopting that proposed modification in this final action. As explained in section III.A.1 of this final notice, we are taking final action to revise 40 CFR 97.921(a), (b), and (c) of the Texas SO_2 Trading Program to condition any exceptions to scheduled allowance recordation activities on Texas' submission *and* EPA's approval of a SIP revision, rather than just on Texas' submission of a SIP revision. This revision will ensure that the program remains fully operational unless it is replaced by a SIP revision that is approved by EPA as meeting SO_2 BART requirements for the covered BART-eligible units.

E. Timing of the Plan for the First Implementation Period

Comment: We received a comment that asserted that the first planning period for regional haze ends in 2018 and given that the Texas SO_2 Trading Program would not be implemented until the beginning of 2019, it followed that the Texas SO_2 Trading Program and any other BART alternative for Texas would not meet the timing requirement for a BART alternative at 40 CFR 51.308(e)(2)(iii). The commenter also argued that EPA's position in the October 2017 final rule that the end of the first planning period of the first long-term strategy for Texas is 2021 and thus the Texas SO_2 Trading Program meets the timing requirement for a BART alternative is unsupported and is inconsistent with EPA's prior statements identifying 2018 as the close of the first planning period. The commenter asserted that EPA's position that the January 2017 revisions to the Regional Haze Rule extended the first planning period contradicts EPA's statements in the January 2017 rulemaking that the revisions to the Regional Haze Rule did not alter the requirements for the first planning period. Additionally, the commenter later asserted, in response to our supplemental proposal to add an assurance level to the Texas SO_2 Trading Program, that EPA cannot guarantee the trading program will actually achieve emissions reductions until the addition of the assurance provisions becomes effective and that given that the limitations imposed by the assurance level would not be implemented until the 2021 compliance period, EPA cannot guarantee that emission reductions under the trading program will actually take place during the first planning period.

A similar comment submitted by New Jersey asserted that the 2017 Regional Haze Rule revisions extended the time to submit Regional Haze plan revisions for the second planning period from 2018 to 2021, but did not extend the date for implementation of BART requirements associated with the first planning period. New Jersey asserted that under the Regional Haze Rule, emission reductions needed in the first planning period are still due by December 31, 2018 and that allowing Texas to obtain the reductions by the end of 2019, as allowed under the Texas SO_2 Trading Program, negates the intent of the CAA (specifically the 10-year planning period to assure incremental progress) and puts additional burden on other contributing states to maintain progress.

Response: After reviewing the Agency's position in the January 2017 final rule making amendments to the Regional Haze Rule, we are not finalizing a position in this action that the first planning period has been extended to July 31, 2021. We agree with the commenter that this position would be at odds with the national finding in the January 2017 action that our amendments there ''do not affect the

[149] 82 FR 48324 at 48327.

development and review of state plans for the first implementation period . . . .'' 82 FR at 3080. Nonetheless, the Texas SO_2 Trading Program satisfies the requirement of 51.308(e)(2)(iii), because, as discussed in section III.A.2 above, the program ensures that emission reductions that were achieved prior to the end of 2018, sufficient to meet the requirements of the BART alternative, will be maintained through an enforceable program.

Actual emission levels from the sources covered by the BART alternative were below the levels mandated by the alternative by the end of the first planning period. In the case of the Texas SO_2 Trading Program, sources subject to the trading program were already emitting SO_2 at levels below the program budget prior to December 31, 2018. As discussed in our November 2019 supplemental proposal, the combined SO_2 emissions from Texas EGUs participating in the intrastate trading program were 179,630 SO_2 tons in 2018, which is well below the Texas SO_2 Trading Program budget of 238,395 tons (as well as the assurance level of 255,083 tons we are finalizing in this action).[150] Therefore, the emissions reductions secured under the trading program occurred prior to the end of the period of the first long-term strategy for regional haze. With the trading program taking effect with the start of the 2019 calendar year, actual emissions were never allowed to exceed the amounts called for by the BART alternative. This issue is further discussed above in section III.A.2. We also note that we have never stated and do not agree that the existing Texas SO_2 Trading Program fails to ensure that all necessary emission reductions will occur by the end of the first planning period even without the addition of the assurance provisions. Our purpose in proposing to add the assurance provisions was merely to further ensure that the program's design is at least as stringent as the CSAPR SO_2 program as applied to Texas, not only on an average annual basis but also in individual years. Given that actual emission levels from the sources covered by the BART alternative were below the levels mandated by the alternative by the end of the first planning period, even before the addition of the assurance level, we are determining that the Texas SO_2 Trading Program meets the timing requirement for a BART alternative at 40 CFR 51.308(e)(2)(iii).

[150] 84 FR 61853.

F. Notice and Comment Requirements

Comment: We received a comment that the FIP promulgating the Texas SO_2 Trading Program did not follow the Clean Air Act's procedural requirements for promulgating a FIP. The commenter claimed that EPA promulgated the FIP without following the public notice and comment procedures set forth in 42 U.S.C. 7607(d)(1)(B), (d)(2)–(6), which the commenter contended violates the Clean Air Act. The commenter contended that the Clean Air Act's public notice and comment procedures at U.S.C. 7607(d)(3) require that EPA first publish in the **Federal Register** a proposed rule that includes a statement of basis and purpose and specifies a comment period. The commenter claimed that this statement of basis and purpose must include a summary of the factual data on which the proposed rule is based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed rule, and that EPA must allow any person to submit comments as well as give interested persons an opportunity for the oral presentation of data, views, or arguments. The commenter asserted that these and other public participation requirements in § 7607(d) build on those in the Administrative Procedure Act and are even more protective of the public's right to notice and comment. The commenter asserted that EPA's January 2017 proposed rule ''established'' source-specific SO_2 emission limits that would have required the installation and operation of modern SO_2 controls or upgraded controls for subject to BART Texas EGUs, and that in contrast to this, the Trading Program in the final rule consisted of an intrastate emissions trading program that was not presented in the proposal. The commenter contended that EPA did not follow the rulemaking procedures required by the CAA given that EPA never proposed the adoption of a trading program nor did it discuss that it might consider adopting an intrastate trading program for Texas in lieu of the source-specific retrofit controls proposed in the January 2017 proposal. Additionally, the commenter asserted that the FIP promulgating the Texas SO_2 Trading Program does not qualify as a logical outgrowth of the January 2017 proposal. The commenter contended that the logical outgrowth doctrine applies where a rule merely clarifies its proposal, or where the agency put commenters on notice that it was considering approaches different from the proposal. According to the commenter, the logical outgrowth doctrine does not apply in this case because (i) the intrastate trading scheme is different than the January 2017 BART proposal, and (ii) EPA did not provide notice that it was considering an intrastate trading program instead of source specific SO_2 emission limits.

Response: We explained in our October 17, 2017 final rule that during the comment period for our January 2017 proposed rule, we received a comment letter from the Texas Commission on Environmental Quality (TCEQ) and the Public Utility Commission of Texas (PUC),[151] urging us to consider as a BART alternative the concept of emission caps using CSAPR allocations. We also received similar comments from Luminant and American Electric Power (AEP). Based on our consideration of these comments and our independent determination that a BART alternative approach under 40 CFR 51.308(e)(2) would meet all regulatory requirements and thus be a viable approach for Texas, we proceeded to address the SO_2 BART requirement for Texas EGUs under a BART alternative consisting of an intrastate trading program in our October 2017 final rule. In response to a petition for reconsideration of the October 2017 final rule requesting that the Administrator reconsider certain aspects of the FIP related to the Texas SO_2 Trading Program, we decided that the October 2017 federal plan could benefit from further public comment.[152] As a result, in our August 27, 2018 proposed rule, we proposed to affirm our October 2017 final rule that approved a portion of the 2009 Texas Regional Haze SIP and promulgated the intrastate trading program FIP. In doing so, we provided the public with an opportunity to comment on all centrally relevant aspects of our Texas SIP approval and of the FIP that promulgated the Texas SO_2 Trading Program, including our proposal to affirm the October 2017 FIP establishing an intrastate trading program capping emissions of SO_2 from certain EGUs in Texas as a BART alternative and our determination that this program satisfies the requirements for a BART alternative. We provided a 60-day public comment period that ended on October 26, 2018, and held a public hearing on September 26, 2018. Following that notice and comment opportunity, the EPA determined that certain additional changes to the program not included in the August 2018 proposal could be warranted. Therefore, we issued a

[151] 82 FR 48324 at 48327.

[152] 83 FR 43586.

supplemental notice of proposed rulemaking on November 14, 2019, providing a 60-day comment period and a public hearing on December 9, 2019. In the November 2019 supplemental proposal,[153] we proposed to amend several provisions of the Texas SO_2 Trading Program with the overall objective of strengthening our finding in the October 2017 final rule,[154] which we proposed to affirm in August 2018,[155] that the Texas SO_2 Trading Program will result in SO_2 emission levels from Texas EGUs that are similar to or less than the emission levels from Texas EGUs that would have been realized had Texas continued to participate in the SO_2 trading program under CSAPR.[156] The amendments to the Texas SO_2 Trading Program we are finalizing in this action are designed to ensure that emission levels in each year under the intrastate trading program, and their aggregate impact on visibility, will be similar to or less than what would have been realized from Texas EGUs from participation in the SO_2 trading program under CSAPR,[157] thus providing further support to our determination that the trading program meets the requirements for a BART alternative. In finalizing our action affirming the intrastate trading program as amended in this final action, the EPA is addressing all in-scope comments we have received on both the August 2018 and November 2019 proposal notices, including, as discussed elsewhere in this final action and in our separate Response to Comments document, comments regarding the lawfulness and basis for the intrastate trading program under the CAA and the Regional Haze Rule, and other related comments. Therefore, to the extent the commenter is alleging that the intrastate trading program in our October 2017 FIP was promulgated without following the public notice and comment procedures and public participation requirements set forth in 42 U.S.C. 7607(d), the agency has cured any such alleged procedural defect.

Comment: We received one comment asserting that EPA cannot claim that the October 2017 trading program was a clarification of the January 2017 proposed rule. The commenter asserted that the Texas SO_2 Trading Program finalized by EPA in the October 2017 final rule differs in substance from the BART proposal, which the commenter claimed is evidenced by EPA's addition in the final action of dozens of pages of regulatory and explanatory text that was not included in the 2017 BART proposal.

Response: We agree that our October 17, 2017 final rule that promulgated an intrastate trading program to address the SO_2 BART requirement for Texas EGUs cannot be characterized as merely a clarification of our January 4, 2017 proposed rule, nor has the Agency made this claim. Based on our consideration of comments we received on the January 2017 proposal urging us to consider as a BART alternative the concept of emission caps using CSAPR allocations, and based on our independent determination that a BART alternative approach under 40 CFR 51.308(e)(2) would meet all regulatory requirements and thus be a viable approach for Texas, we proceeded to address the SO_2 BART requirement for Texas EGUs under a BART alternative consisting of an intrastate trading program in our October 2017 final rule. In that final rule, EPA considered and responded to all relevant comments germane to the final rule and provided a record of decision-making for the final action. We note that some of the comments we received on the January 2017 proposal raised specific issues related to our proposed analyses for the source-specific BART emission limits we proposed. Given that those source-specific emission limits were not part of our final action, providing substantive responses to such comments was not required as they were no longer relevant. As discussed in several places throughout this final action, in response to a petition for reconsideration of the October 2017 final rule requesting that the Administrator reconsider certain aspects of the FIP related to the Texas SO_2 Trading Program, we provided an opportunity for further public comment on all centrally relevant aspects of the Trading Program in a proposal published on August 27, 2018, and provided an opportunity for public comment on proposed amendments to certain provisions of the Trading Program in a supplemental proposal published on November 14, 2019. The amendments to the Texas SO_2 Trading Program we are finalizing in this final action, which include minor changes from what we proposed in the November 2019 proposal, are designed to ensure that emission levels in each year under the intrastate trading program, and their aggregate impact on visibility, will be similar to or less than what would have been realized from Texas EGUs from participation in the SO_2 trading program under CSAPR,[158] thus providing further support to our determination that the Texas SO_2 Trading Program meets the regulatory requirements for a BART alternative and is an appropriate approach for addressing Texas' SO_2 BART obligations.

Comment: We received one comment contending that the Texas SO_2 Trading Program cannot be characterized as a logical outgrowth of the December 2014 proposed rule given that the BART provisions in the December 2014 proposed rule were abandoned due to *Homer City II,* and that EPA otherwise took final action on that proposed rule in a final action published in January 2016. The commenter also asserted that further confirmation that the December 2014 proposal was part of a different rulemaking process is provided by the fact that in the January 2017 BART proposal, EPA did not invite comments on the December 2014 proposal and also that EPA did not include the December 2014 proposal or any of the supporting technical analysis for the December 2014 proposal in the docket for the January 2017 proposal on the date of the publication of the proposed rule, as required by the CAA at 42 U.S.C. 7607(d)(3).

Response: This commenter is referring to our December 16, 2014 proposed rule in which we proposed, among other things, to rely on our CSAPR FIP requiring Texas sources' participation in the CSAPR trading programs to satisfy the NO_X and SO_2 BART requirements for Texas' BART-eligible EGUs.[159] Due to the uncertainty arising from the D.C. Circuit's remand of Texas' CSAPR budgets, when we finalized the December 2014 proposal in an action published in January 2016, we did not finalize our proposal to rely on CSAPR to satisfy the SO_2 and NO_X BART requirements for Texas EGUs.[160] We note that we did not attempt to characterize the Texas SO_2 Trading Program as a logical outgrowth of the December 2014 proposed rule. We agree that the December 2014 proposed rule was a part of a different rulemaking process, which is supported by the fact that we did not reference that proposed rule in developing the intrastate trading program that was finalized in October 2017. We also did not reference the December 2014 proposal in our August 2018 proposal to affirm the October 2017 final rule.

Comment: We received a comment from environmental groups asserting that the fact that Texas state agencies and industry submitted comments in

[153] 84 FR 61850, 61851.

[154] 82 FR 48324, 48329.

[155] 83 FR 43591.

[156] *See* 83 FR at 43599.

[157] 83 FR 43592.

[158] 83 FR 43592.

[159] 79 FR 74818.

[160] *See* 81 FR 296, 301–02 (Jan. 5, 2016).

support of a trading program does not make the October 2017 final rule promulgating the Texas SO_2 Trading Program a ''logical outgrowth'' of EPA's 2014 proposal given that EPA did not provide notice to the public that it was proposing or even considering a trading program. The commenter asserted that the D.C. Circuit has ''made clear that the fact that some commenters actually submitted comments addressing the final rule is of little significance. The agency must itself provide notice of a regulatory proposal,'' citing *Ass'n of Private Sector Colls.* v. *Duncan,* 681 F.3d 427, 462 (D.C. Cir. 2012) (citation omitted) (internal quotation marks omitted). The same environmental groups asserted that they did not have an opportunity to comment on information that arose in the October 2017 final rule promulgating the Trading Program, including the consideration of a trading program as a BART alternative to satisfy BART, the specifics of EPA's intrastate trading program, or the rationale for adopting that program. The environmental groups asserted that while they submitted comments on BART alternatives in response to the comments submitted by industry—those comments were not based on, or responding to, any actual or implied proposal by EPA to adopt such an alternative. The environmental groups contended that their response to industry comments about industry's desire for a trading program is not a substitute for having notice and opportunity to comment on EPA's decision to promulgate a trading program.

Response: We do not take the position that any comments on the January 2017 proposal could have or did provide a basis for treating the October 2017 final rule as a ''logical outgrowth'' of the December 2014 proposal, so the premise of this comment is incorrect. Furthermore, the case cited by commenter is inapposite as it does not arise under the CAA. The CAA contemplates circumstances in which the Agency may finalize rules under section 307(d) that reflect changes from proposal that a commenter is unable to comment on. The appropriate remedy, when circumstances warrant, is administrative reconsideration, so that the agency is able to provide the public the opportunity to comment on those matters (or ''objections'') that are of ''central relevance'' to the outcome of the rule. *See Wisconsin* v. *EPA,* 938 F.3d 303, 331–32 (D.C. Cir. 2019). The commenter's concerns regarding logical outgrowth have now been addressed by our August 27, 2018 proposal that specifically solicited comment on all key aspects of the Texas SO_2 Trading Program. We are finalizing that proposal with amendments to certain provisions of the Trading Program after considering and responding to all comments within scope that we received during the public comment periods for the August 2018 proposal and the November 2019 supplemental proposal.

Comment: We received comments from environmental groups asserting that EPA did not provide responses to certain comments they submitted during the public comment period for our January 2017 proposal. Those particular comments submitted by the environmental groups were a reaction to comments submitted by industry to EPA—also during the public comment period for our January 2017 proposal—urging us to consider as a BART alternative the concept of emission caps using CSAPR allocations in place of source-specific SO_2 BART controls. Specifically, the comments the environmental groups claim EPA did not respond to asserted that CSAPR is not better than BART. The commenters contended that EPA had an obligation to respond to those comments given EPA's reliance on CSAPR to justify the Texas SO_2 Trading Program, and that in not providing a response, EPA violated the CAA's requirement that a rule ''be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.'' 42 U.S.C. 7607(d)(6)(B).

Response: We provided responses in the October 2017 final rule to each of the in-scope significant comments, criticisms, and new data submitted in written or oral presentations during the comment period. We continue to hold the position that comments alleging that CSAPR is not better than BART were beyond the scope of our January 4, 2017 proposed rule, and they are beyond the scope of our final action now. We continue to believe that such comments raise issues that are appropriately addressed in the record of the 2012 CSAPR Better-than-BART rule [161] and our 2017 affirmation of CSAPR Better-than-BART.[162] In this action, the EPA is relying on the conclusion reached in those actions, without reopening them or having any intention to reopen them, that CSAPR remains a valid BART-alternative, including after taking account of geographic changes in the scope of CSAPR's coverage since 2012. In particular, because the Texas SO_2 Trading Program, as amended in this final action, has been designed to achieve SO_2 emission levels from Texas EGUs that are similar to or less than what would have been realized from Texas EGUs' participation in the CSAPR SO_2 trading program, we are making the determination that the Texas SO_2 Trading Program is an appropriate BART alternative for addressing Texas' SO_2 BART obligations. Because the Texas SO_2 Trading Program will result in SO_2 emissions from Texas EGUs similar to or less than emissions anticipated under CSAPR, this alternative is an appropriate approach for addressing Texas' SO_2 BART obligations and, in the context of the operation of the CSAPR ozone-season NO_X trading program and the operation of the CSAPR annual NO_X and SO_2 trading programs, will achieve greater reasonable progress than BART towards restoring visibility, consistent with the June 2012 ''CSAPR Better-than-BART'' determination and September 2017 ''CSAPR Better-than-BART affirmation finding.'' As discussed in section I.D of this final action, EPA has denied a petition for reconsideration of the 2017 CSAPR Better-than-BART affirmation that was based in part on an objection that the Texas program is not of sufficient stringency to satisfy the analysis for CSAPR. Although our determination in that action is also beyond the scope of this action here, it means that EPA here can continue to rely on the CSAPR ''Better-than-BART'' finding in conducting its analysis of whether the Texas intrastate trading program satisfies the requirements of 40 CFR 51.308(e)(2).

Comment: One commenter asserted that EPA's August 2018 proposal affirming the October 2017 final rule promulgating the Texas SO_2 Trading Program and solicitation of comments on only some elements of the Texas SO_2 Trading Program cannot cure the rule's procedural deficiencies in finalizing the trading program because the opportunity for public comment is both insufficient and too late. The commenter contended that based on case law, the purpose of notice and comment is to provide the public with an opportunity to influence agency rulemaking, citing *U.S. Steel Corp.* v. *EPA,* 595 F.2d 207, 215 (5th Cir. 1979); *Nat'l Tour Brokers Ass'n* v. *U.S.,* 591 F.2d 896, 902 (D.C. Cir. 1978). The commenter claimed that this opportunity to influence agency rulemaking is meaningful only when rules remain in the formative stage and agencies are more likely to give real consideration to alternative ideas. Furthermore, the commenter asserted

[161] 77 FR 33641.

[162] 81 FR 74504.

that agencies do not provide an adequate opportunity to influence the rulemaking process when they solicit public comment on rules that they have already labeled as final, as in the case of the Texas SO_2 Trading Program. The commenters stated that the October 2017 FIP promulgating the Texas SO_2 Trading Program remained in effect even while it was open to public comment, thus not providing the public with a meaningful opportunity to influence the trading program. Additionally, the commenter noted that EPA has not yet rescinded or withdrawn the FIP promulgating the Texas SO_2 Trading Program even though environmental groups filed a petition for reconsideration arguing that the Texas SO_2 Trading Program did not follow notice and comment requirements. According to the commenters, in having the Texas SO_2 Trading Program remain in effect, EPA has continued to violate the CAA's notice and comment provisions.

The commenter asserted that the D.C. Circuit explained in *Nat'l Tour Brokers Ass'n,* 591 F.2d at 902, that agencies are likely to become more close-minded and defensive once they put their credibility on the line in the form of final rules. Furthermore, the commenter argued that agencies cannot cure notice and comment defects by merely soliciting comments after the promulgation of a final rule. The commenter asserted that when an agency seeks to save a rule that suffers from a notice and comment violation, that agency bears the burden of proving that the violation did not prejudice the public and that the absence of such prejudice must be clear for the violation to be considered ''harmless'' and the rule to be upheld. The commenter claimed that at this point, the only legal remedy is for EPA to withdraw the Texas SO_2 Trading Program and replace it with a FIP that satisfies the statutory and regulatory requirements.

Response: In response to the petition for reconsideration referenced by the commenters, we decided that the October 2017 final rule could benefit from further public comment.[163] As a result, in our August 2018 proposed rule, we proposed to affirm our FIP promulgating the Texas SO_2 Trading Program and in doing so, we provided the public with an opportunity to comment on all centrally relevant aspects of the October 2017 final rule, including our promulgation of the Texas SO_2 Trading Program and our determination that this program satisfies the requirements for a BART alternative.[164] We disagree with the commenter that the opportunity for public comment provided by our August 27, 2018 proposed rule is insufficient and too late. While the October 2017 final rule remained in effect when we proposed the August 27, 2018 proposal, in that proposal we also sought input on whether SO_2 BART would be better addressed through a source-by-source approach (source-specific BART), the October 2017 SO_2 trading program, or some other appropriate BART alternative. We stated in the August 27, 2018 proposal that if we were to decide to act pursuant to any comments we receive, we may initiate a new rulemaking process with a new proposed rule.[165] We provided a 60-day public comment period that ended on October 26, 2018 and held a public hearing on September 26, 2018, to receive public comment on our August 27, 2018 proposed rule. As a result of comments received during that comment period, we subsequently published and took further comment on a supplemental proposal in November 2019 to make changes to certain provisions of the Texas SO_2 Trading Program. Our November 2019 supplemental proposal and the amendments to the trading program we are finalizing in this action are evidence that our intent was to be open to further comment and that we ultimately gave real consideration and were influenced by the comments we received. Therefore, we disagree that we have not provided the public a fully adequate opportunity to influence the agency's rulemaking or that the public notice and opportunity to comment on our proposals was not meaningful.

In this respect, our actions are consistent with the requirements of the CAA under section 307(d). The CAA contemplates that in some circumstances the public may not be able to comment on important aspects of a final rule. The appropriate remedy is reconsideration to afford that opportunity for comment, and thus provide for administrative exhaustion prior to judicial review, with respect to all ''centrally relevant'' objections to the final rule. The August 2018 proposal afforded the opportunity to comment on all such objections with respect to the October 2017 final action.

The CAA also contemplates that a final rule may remain in effect while the EPA undertakes that reconsideration. Even when the EPA is undertaking a mandatory reconsideration process under section 307(d)(7)(B), the statute provides that the rule ''*may* be stayed'' (emphasis added) by the Administrator or a court for a period not to exceed three months. The fact that the Texas SO_2 Trading Program remained in effect and went into operation during the pendency of the public notice and comment periods in this instance does not in any manner establish that the agency's notice and comment process on the August 2018 proposal to reaffirm the final rule is somehow infirm, or that any alleged defects in the procedure for the October 2017 final rule are somehow incurable.

Further, the cases cited by commenter are inapposite because they were not subject to the provisions of CAA section 307(d). In *U.S. Steel Corp.* v. *EPA,* 595 F.2d 207 (5th Cir. 1979), for instance, the court reviewed EPA's designation of nonattainment areas under section 107 of the Act. Designations under section 107 are not amongst the enumerated actions in section 307(d) of the Act that are governed by the administrative rulemaking procedures of subsection (d), including the provision for mandatory reconsideration under section 307(d)(7)(B). Thus, the court in *U.S. Steel Corp.* was reviewing EPA's action under the Administrative Procedure Act. *See* 595 F.2d at 210. The Texas SO_2 Trading Program is a federal implementation plan promulgated under section 110(c) of the CAA, and thus subject to section 307(d), pursuant to section 307(d)(1)(B). The court in *U.S. Steel* was not confronted with a circumstance in which the agency promulgated a final rule subject to the provisions of CAA section 307(d) that was substantially different from the proposal, but then took the necessary steps to provide the opportunity for comment on all centrally relevant issues, consistent with the process contemplated in section 307(d)(7)(B). Thus, the *U.S. Steel Corp.* case cited by the commenter is not relevant to our final action on the Texas SO_2 Trading Program here.

Comment: One commenter expressed general concern that EPA proposed to affirm the October 2017 final rule that promulgated the Texas SO_2 Trading Program in the August 2018 proposal without soliciting comments on certain sections of the final rule.

Response: In response to a petition for reconsideration of the October 2017 final rule requesting that the Administrator reconsider certain aspects of the FIP related to the Texas SO_2 Trading Program, we decided that important aspects of the October 2017 federal plan could benefit from further

[163] 83 FR 43586.

[164] 83 FR 43586 at 43590.

[165] 83 FR at 43587.

public comment.[166] Accordingly, in a notice published on August 27, 2018, we proposed to affirm certain aspects of the October 2017 final rule, and thus opened for comment the following elements, which effectively covered all of the central objections in the petition for reconsideration: (1) The proposal to affirm the October 2017 FIP establishing an intrastate trading program addressing emissions of SO_2 from certain EGUs in Texas as a BART alternative and the determination that this program satisfies the requirements for BART alternatives; (2) the proposal to affirm the finding that the BART alternatives in the October 2017 rulemaking to address SO_2 and NO_X BART at Texas' EGUs result in emission reductions adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for the following NAAQS: 1997 8-hour ozone, 1997 $PM_{2.5}$ (annual and 24-hour), 2006 $PM_{2.5}$ (24-hour), 2008 8-hour ozone, 2010 1-hour NO_2, and 2010 1-hour SO_2 NAAQS; and (3) the proposal to affirm our October 2017 approval of Texas' SIP determination that no sources are subject to BART for PM. The August 2018 affirmation proposed rule also solicited comment on the specific issues of whether recent shutdowns of sources included in the trading program and the merger of two owners of affected EGUs should impact the allocation methodology for certain SO_2 allowances. In addition to soliciting comment on the above elements and aforementioned specific issues, the August 2018 affirmation proposal also invited comment on additional issues that could inform our decision making with regard to the SO_2 BART obligations for Texas. First, we sought input on whether SO_2 BART would be better addressed through a source-by-source approach (source-specific BART), the October 2017 SO_2 trading program, or some other appropriate BART alternative. Second, EPA requested comment on whether a SIP-based program would serve Texas better than a FIP. Third, we requested public input on whether and how the SO_2 trading program finalized in the October 2017 final rule addresses the long-term strategy and reasonable progress requirements for Texas. We find that the issues that EPA enumerated for reconsideration and solicitation of public comment covered all centrally relevant aspects of the October 2017 rule. *See* 83 FR at 43587. As noted by the commenter, we recognize that there were certain aspects of our October 2017 final rule that we did not reopen and thus did not solicit further comment on in our August 2018 proposal. We did not reopen or solicit comment on the following: our October 2017 final determination that CSAPR addresses the NO_X BART requirements for EGUs in Texas; identification of BART-eligible sources; and our determination that the BART-eligible EGUs not participating in the Texas SO_2 Trading Program were not causing or contributing to visibility impairment, and were therefore not subject to BART. We did not reopen and solicit further comment on these determinations made in the October 2017 final rule because these aspects of our final rule were finalized as proposed in the January 2017 proposal after carefully considering and responding to all comments within scope that we received during the public comment period.

G. Subject-to-BART Determinations

Comment: We received a comment from Lower Colorado River Authority (LCRA) stating their Fayette Power Plant Units 1 & 2 (FPP U1 & U2) are not subject to BART, contrary to the determination made by EPA in the January 2017 FIP proposal. The commenter asserted that EPA improperly used data from 2000–2004, which pre-dated the installation of wet flue gas desulfurization scrubbers at the units, to assess visibility impacts of FPP U1 & U2. Although the commenter did not request that EPA remove FPP U1 & U2 from the Texas SO_2 Trading Program at this time, and actually expressed support of the Texas FIP and the inclusions of FPP U1 & U2 in the trading program, the commenter requested that EPA concur that the most currently available data must be used for visibility impact determinations under the regional haze program.

Response: We appreciate LCRA's concerns regarding Fayette Power Plant Units 1 and 2, and we agree that Fayette Units 1 and 2 are currently equipped with high performing wet FGDs. We note that, as discussed in our October 2017 final rule and as affirmed in this rulemaking, we are not making a subject-to-BART determination for those sources covered by the Texas SO_2 Trading Program. The relevant BART requirement for the participating BART-eligible units are encompassed by BART alternatives for NO_X and SO_2 such that we did not deem it necessary to finalize subject-to-BART findings for these EGUs. In addition, we are affirming our approval of the determination in the 2009 Texas Regional Haze SIP that none of these sources are subject to BART for PM. Therefore, comments concerning the emissions utilized in our subject-to-BART modeling for the sources participating in the SO_2 trading program are no longer relevant.

H. Visibility Transport

Comment: One commenter asserted that EPA's reliance on the Texas SO_2 Trading Program to satisfy section 110(a)(2)(D)(i)(II) is arbitrary and capricious both because the Texas SO_2 Trading Program itself is unlawful and because EPA's reliance on the Texas SO_2 Trading Program here is based on EPA's claims that the Texas SO_2 Trading Program reduces emissions as much as CAIR would have. According to the commenter, this is problematic because EPA cannot use CAIR, given that CAIR was invalidated years ago by the D.C. Circuit, citing *North Carolina,* 531 F.3d at 903, and has been replaced by CSAPR. Thus, the commenter contended that EPA cannot use CAIR as the benchmark for whether the interstate visibility transport requirements are met. The commenter also asserted that EPA disapproved Texas' regional haze plan precisely because it relied on CAIR and that it is arbitrary and capricious for EPA to now turn around and claim that interstate visibility transport requirements are satisfied because the emissions reductions in CAIR will be achieved.

The commenter also asserted that EPA's new rationale of relying on the emission levels assumed in the CENRAP modeling as a basis for finding that Texas' emissions will not interfere with other states' visibility plans is not appropriate given that there is no demonstration provided to show that the emission assumptions used by CENRAP in its visibility modeling are in fact sufficient to assure that Texas emissions do not interfere with measures required to protect visibility in other states. The commenter also expressed concern that certain states, such as New Mexico and Colorado, impacted by Texas emissions are not members of CENRAP, and therefore, the CENRAP process could not have determined what emissions limits were necessary to satisfy Texas' visibility transport obligations with respect to New Mexico and Colorado.

Response: First, we address comments regarding the Texas SO_2 Trading Program as being unlawful, arbitrary, or capricious, elsewhere in this document. Second, the Texas SO_2 Trading Program, as promulgated in October 2017 and with the amendments promulgated in this final rule, results in emission reductions that are adequate to satisfy Texas' visibility transport obligations under CAA section 110(a)(2)(D)(i)(II) for the following six NAAQS: (1) 1997 8-hour ozone; (2) 1997 $PM_{2.5}$ (annual and

[166] 83 FR 43586.

24 hour); (3) 2006 $PM_{2.5}$ (24-hour); (4) 2008 8-hour ozone; (5) 2010 1-hour NO_2; and (6) 2010 1-hour SO_2. The 2009 Texas Regional Haze SIP relied on participation in CAIR to meet the SO_2 BART requirements for Texas EGUs, and this level of emissions reductions from Texas is what other states relied upon and assumed during interstate consultation and in the development of their long-term strategies and reasonable progress goals for their own Class I areas in their regional haze SIPs. As discussed in section III.B of this notice, Texas EGU sources were projected to emit approximately 350,000 tons of SO_2 annually under CAIR participation. By comparison, Texas EGUs are anticipated to emit no more than approximately 290,083 tons of SO_2 annually under the Texas SO_2 Trading Program (*i.e.,* 255,083-ton assurance level + estimated 35,000 tons per year of emissions from units not covered by the Texas SO_2 Trading Program), which is well below the 350,000-ton emissions projection for Texas sources under CAIR and well below the maximum total annual SO_2 emissions assumed for Texas under CSAPR (*i.e.,* 317,000 tons) in the CSAPR Better-than-BART analysis. Thus, the Texas SO_2 Trading Program as amended in this final action, ensures SO_2 emission reductions from Texas that are consistent with, and indeed greater than, the level of emission reductions relied upon by other states during interstate consultation and thus this level of emissions reductions is adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for the six identified NAAQS.[167]

The commenter makes the claim that CENRAP's modeling of emission assumptions does not necessarily demonstrate that those assumptions were in fact sufficient to assure non-interference by Texas' emissions with measures required to protect visibility in other states. We note that our 2013 infrastructure-SIP guidance addressing the interstate visibility transport requirements of the Act (also sometimes referred to as ''prong 4'') lays out two ways in which a state's infrastructure SIP submittal may satisfy these requirements.[168] One way is through a state's confirmation in its infrastructure SIP submittal that it has an EPA-approved regional haze SIP in place. In the absence of a fully approved regional haze SIP, the second method to meet these requirements is a demonstration that emissions within a state's jurisdiction do not interfere with other states' plans to protect visibility. Such a demonstration should point to measures that limit visibility-impairing pollutants and ensure that the resulting reductions conform with any mutually agreed emission reductions under the relevant regional haze regional planning organization (RPO) process.[169] Given that the emissions under the Texas SO_2 Trading Program—including the assurance provisions—are less than the level of Texas emissions reductions agreed upon by Texas and other states during consultation and assumed and relied upon in those other states' regional haze SIPs, we continue to find that the FIP is adequate to ensure that emissions from Texas do not interfere with measures to protect visibility in nearby states.

The commenter also makes the claim that there is no rational basis for EPA's reliance on the emission levels assumed in CENRAP modeling as a basis for finding that Texas' emissions will not interfere with other states' visibility plans given that there are states whose visibility is impacted by Texas that are not members of CENRAP. Our basis for determining that the FIP is adequate to ensure that emissions from Texas do not interfere with measures to protect visibility in nearby states is that the emissions reductions secured under the Texas SO_2 Trading Program are consistent with the level of emissions reductions relied upon by other states during consultation, which is not limited to consultation amongst CENRAP states.[170] The Regional Haze Rule requires that ''Where a state has emissions that are reasonably anticipated to contribute to visibility impairment in any mandatory Class I Federal area located in another State or States, the State must consult with the other State(s) in order to develop coordinated emission management strategies.'' [171] Clearly, this requirement applies regardless of whether the impacted states are members of the same regional planning organization (RPO) or not. Thus, Texas had an obligation to consult with states, both in and outside of CENRAP, whose Class I areas are potentially impacted by Texas emissions. As documented in the 2009 Texas Regional Haze SIP,[172] Texas participated in inter-regional planning organization calls during the SIP development process for the first planning period. Texas also sent consultation letters to Oklahoma, Louisiana, Missouri, Arkansas, Colorado and New Mexico. Included with each letter was a discussion of the CENRAP Particulate Matter Source Apportionment Technology (PSAT) modeling determining the contribution from each Texas source area to visibility impairment at Class I areas in the given state. In the 2009 SIP, Texas asserted that it participated fully in the analysis of this data, including estimation of the base period visibility impairment, natural visibility condition estimates, and 2018 projections based on current (at that time) and anticipated future state and federal controls. For states outside of CENRAP, Texas documented in its 2009 SIP that Colorado's Department of Public Health and Environment confirmed in a letter dated June 24, 2008, that no further emissions reductions were requested of Texas at that time. Texas also documented that as of December 2008, shortly before its submission of the final SIP to EPA on March 19, 2009, New Mexico had not responded to Texas' letter to confirm whether or not New Mexico was expecting any additional emission reductions from Texas sources. Furthermore, New Mexico did not include in its Regional Haze SIP any additional emission reductions expected from Texas sources. The Texas emissions reductions that will result from the Texas SO_2 Trading Program and Texas' participation in CSAPR for ozone season NO_X are consistent with the level of Texas emissions reductions relied upon by other states both in and outside CENRAP during consultation with Texas.

It is incorrect to claim that because CAIR was invalidated, EPA and the states can no longer use the anticipated emissions and reasonable progress goals established through the consultation process for the first planning period. Those goals may have been established in part based on expectations of emissions performance under CAIR, but the anticipated emissions reductions and the goals for regional haze purposes remain in effect (though we note that reasonable progress goals are not binding). Thus, this level of emissions

[167] 83 FR 43605.

[168] *See* ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under CAA sections 110(a)(1) and 110(a)(2)'' (September 13, 2013).

[169] *See id.* ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under CAA sections 110(a)(1) and 110(a)(2),'' at 34 (September 13, 2013). *See also* 76 FR 22036 (April 20, 2011) (containing EPA's approval of the visibility requirement of 110(a)(2)(D)(i)(II) based on a demonstration by Colorado that did not rely on the Colorado Regional Haze SIP).

[170] See CFR 51.308(d)(3)(i)–(iii) addressing the requirements for consultation with other states.

[171] 40 CFR 51.308(d)(3)(i).

[172] See 2009 Texas Regional Haze SIP, section 4.3 titled ''Consultations On Class I Areas In Other States.'' The submittal can be found in *Regulations.gov* docket ID EPA–R06–OAR–2016–0611, document EPA–R06–OAR–2016–0611–0002.

provides an appropriate benchmark for assessing whether states are adequately addressing interstate visibility transport (when such a demonstration is necessary). We note that this is different than situations in which states have attempted to rely on CAIR as a BART alternative despite the fact that CAIR is no longer in operation. Here, the fact that CAIR no longer exists and has been replaced by CSAPR does not impact the legitimacy of the level of emission reductions agreed upon through the consultation process among states, particularly given that CSAPR is generally more stringent than CAIR. And here, the Texas program is designed to be more stringent than CSAPR would have been for SO_2 emissions in Texas. See section III.B where we provided detailed analysis of anticipated emissions under CAIR and the Texas program. Therefore, we find that Texas' visibility transport obligations under CAA section 110(a)(2)(D)(i)(II) for the six NAAQS listed above are satisfied.

Comment: We received one comment asserting that since EPA has not made any determination of the trading program's visibility impacts on other states, we cannot make the claim that the Texas SO_2 Trading Program was designed to meet the CAA's visibility transport requirements. The commenter claimed that EPA cannot lawfully claim that the Texas SO_2 Trading Program was designed to meet the visibility transport requirements of the CAA because the CAA's visibility good neighbor provision requires and authorizes EPA to prohibit only those upwind emissions that interfere with measures required to be included in the applicable implementation plan for any other State. The commenter cited 42 U.S.C. 7410(a)(2)(D)(i)(II), as well as *E.P.A.* v. *EME Homer City Generation, L.P.,* 134 S.Ct. 1584, 1604 (2014) and *EME Homer City II,* 795 F.3d at 127. The commenter asserted that if one applies to this case the Supreme Court's precedent interpreting the analogous good neighbor provision under Section 7410(a)(2)(D)(i)(I), EPA is not required and does not have authority to regulate upwind emissions unless it first makes the predicate finding that those upwind emissions interfere with downwind visibility. The commenter further asserted that if the EPA makes that finding, even then it may only regulate upwind emissions up to the amounts of pollution that actually interfere with downwind visibility, again citing *EPA* v. *EME Homer City Generation, L.P.,* 134 S.Ct. 1584, 1603 (U.S. 2014) and *EME Homer City II,* 795 F.3d at 127. The commenter contended that in affirming its October 2017 final rule that promulgated the Texas SO_2 Trading Program, EPA failed to make the predicate finding that emissions from Texas are interfering with downwind states' attainment of the NAAQS and that EPA, therefore, cannot properly claim that the Texas SO_2 Trading Program was designed to meet the agency's good neighbor ''requirement'' to protect downwind visibility from ''interfere[nce].''

Response: We disagree that the Texas SO_2 Trading Program cannot be viewed as a program ''designed to meet a requirement other than BART'' for purposes of the BART alternative analysis under 40 CFR 51.308(e)(2)(i)(C). As relevant to this comment, the Texas program is designed, among other things, to ensure reductions of SO_2 emissions from EGU sources in Texas that meet (and indeed are more stringent than) the reductions agreed to in the interstate consultation process for setting RPGs for Class I areas in other states. See section III.B of this notice, where we explain that the Texas SO_2 Trading Program as amended in today's final action ensures emission reductions in Texas that are adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for six NAAQS.

We disagree with the commenter that EPA has not made allegedly necessary predicate findings under prong 4 in order to claim that the Texas program is designed to meet prong 4 requirements. The commenter incorrectly attempts to import into the interstate visibility transport analysis under prong 4 the policy determinations, regulatory design, and associated case law of the ''good neighbor provision'' at 110(a)(2)(D)(i)(I), related to addressing significant contribution to nonattainment and interference with maintenance of the NAAQS in other states, which we commonly refer to as prongs 1 and 2. Those precedents are not necessarily applicable given that the agency has long had a different framework for analysis under prong 4, with an entirely different set of policy guidance and administrative precedents. As explained above, our interpretation of section 110(a)(2)(D)(i)(II) with respect to visibility transport is that one of the pathways by which a state can meet its visibility transport obligations is through a demonstration that emissions within a state's jurisdiction do not interfere with other states' plans to protect visibility. EPA's September 13, 2013 guidance explains that such a demonstration should point to measures that limit visibility-impairing pollutants and ensure that the resulting reductions conform with any mutually agreed emission reductions under the relevant regional haze regional planning organization (RPO) process.[173] This has been EPA's long-standing interpretation of how a state's visibility transport obligations can be satisfied, and we have since approved many SIPs and promulgated FIPs that address CAA section 110(a)(2)(D)(i)(II) with respect to visibility transport through this pathway. Texas participated in the CENRAP process in developing its SIP for the first planning period and relying on the technical work developed through that process, Texas identified states with Class I areas impacted by Texas emissions and those states agreed that they are being impacted by emissions from Texas sources. Furthermore, through the consultation process, Texas made a commitment to states with Class I areas impacted by emissions from Texas sources that it would implement CAIR to satisfy its BART requirements and those states agreed with Texas that anticipated emission reductions due to the implementation of CAIR would be sufficient to address Texas' impacts at their Class I areas. The impacted states relied on this level of emission reductions from Texas sources in developing their SIPs and establishing their RPGs. As discussed in section III.B. of this action, given that the revisions to the Texas SO_2 Trading Program we are finalizing in today's final action ensure emission reductions consistent with and below the emission levels agreed upon by all states during interstate consultation under 40 CFR 51.308(d)(3)(i)–(iii) and relied upon by states impacted by Texas emissions, we find that these revisions provide further support for our earlier finding that the BART alternative in the October 2017 FIP results in emission reductions adequate to satisfy the requirements of CAA section 110(a)(2)(D)(i)(II) with respect to visibility for the six identified NAAQS.[174]

Further, EPA has requisite FIP authority under CAA section 110(c) to address prong 4 for the six NAAQS for

[173] See ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under CAA sections 110(a)(1) and 110(a)(2),'' at 34 (September 13, 2013). See also 76 FR 22036 (April 20, 2011) containing EPA's approval of the visibility requirement of 110(a)(2)(D)(i)(II) based on a demonstration by Colorado that did not rely on the Colorado Regional Haze SIP.

[174] See 2009 Texas Regional Haze SIP, section 4.3 titled ''Consultations On Class I Areas In Other States.'' The submittal can be found at *www.regulations.gov,* Docket ID EPA–R06–OAR–2016–0611, Document ID EPA–R06–OAR–2016–0611–0002.

Texas, given our disapproval of the state's prong 4 submittals. *See* 82 FR at 48332. Thus, our position is that we have the obligation and authority to address Texas' interstate visibility transport obligations. With the emission levels established by the Texas SO_2 Trading Program, as promulgated in October 2017 and amended by this final rule, we affirm our finding that the emission levels assumed in the CENRAP modeling are in fact sufficient to assure that Texas' emissions do not interfere with other states' visibility plans, and that Texas is achieving emission reductions that satisfy prong 4 obligations with respect to the six aforementioned NAAQS. For the reasons just discussed, we can also determine that the intrastate program is ''designed to meet a requirement other than BART'' for purposes of 51.308(e)(2)(i)(C).

We also disagree with the comment that EPA does not have the authority to regulate Texas' emissions with respect to visibility without first making the finding that emissions from Texas are interfering with downwind states' attainment of the NAAQS. The visibility prong (or ''prong 4'') of CAA section 110(a)(2)(D)(i)(II) requires that the implementation plan submitted by a state contain adequate provisions prohibiting any source or other type of emissions activity within the State from emitting any air pollutant in amounts that will interfere with measures required to be included in the applicable implementation plan for any other state to protect visibility. Prong 4 is concerned with visibility and there is no requirement that EPA first make a finding that a state is interfering with downwind states' attainment of the NAAQS before approving a SIP or promulgating a FIP that addresses CAA section 110(a)(2)(D)(i)(II) with respect to visibility transport.

While the commenter is correct that the regional planning process by which Texas and surrounding states developed their regional haze SIPs took place more than a decade ago and in the interim CAIR has been invalidated and replaced by CSAPR, given that the implementation of CAIR in Texas is what Texas committed to and what impacted states agreed with and relied upon in developing their own regional haze SIPs, we continue to find that it is appropriate to compare the emissions reductions anticipated from CAIR to the Texas SO_2 Trading Program to determine whether the FIP is adequate to ensure that emissions from Texas do not interfere with measures to protect visibility in nearby states as required under CAA section 110(a)(2)(D)(i)(II). We recognize that the process of taking action on certain SIPs related to regional haze for the first planning period and interstate visibility transport has taken longer than EPA originally anticipated when it first promulgated the Regional Haze Rule in 1999. Notwithstanding this delay, we do not believe it would be reasonable or practical at this time to require states with outstanding visibility transport obligations to revisit and/or update their emission reduction commitments to impacted states for the first implementation period. Such a process could potentially be time and resource intensive at a time when states are currently focusing their attention on developing regional haze implementation plans for the second implementation period. Thus, we do not believe it would not be reasonable or practical at this time to require Texas to revisit its emission reduction commitments to states with Class I areas impacted by Texas emissions for the first implementation period.

We address other comments that EPA must analyze BART on a source-by-source basis elsewhere in this document.

I. Reasonable Progress

Comment: We received a comment asserting that the Texas SO_2 Trading Program cannot possibly be designed to satisfy the reasonable progress requirements for several reasons. As an initial matter, the commenter claimed that EPA was attempting to bypass the source-specific analyses required under § 51.308(e)(2)(i)(C) by simply asserting that the trading program was designed to be part of the long-term strategy to meet reasonable progress requirements. Additionally, the commenter asserted that EPA's claim that the Texas SO_2 Trading Program is somehow designed to meet the reasonable progress requirements is contradicted by EPA's statement elsewhere in the August 2018 affirmation proposal that it is not taking action on the reasonable progress elements that the Fifth Circuit remanded to the agency. The commenter also claimed that setting aside this inconsistency, the Texas SO_2 Trading Program cannot be designed to satisfy the reasonable progress requirements given that it makes no progress at all as the allowances available under the trading program exceed the covered sources' emissions in 2015, 2016, and 2017, and thus the Texas SO_2 Trading Program will not reduce emissions or improve visibility. Furthermore, the commenter asserted that the Texas SO_2 Trading Program cannot possibly be designed to satisfy the reasonable progress requirements because EPA did not consider the four statutory factors for reasonable progress. The commenter asserted that EPA must conduct a four-factor analysis of whether pollution controls are needed at individual sources—whether subject to BART or not—to make reasonable progress and that the Texas SO_2 Trading Program and the Q/d analysis that helped inform the trading program cannot act as a substitute for a four-factor reasonable progress analysis given that there are no statutory or regulatory exemptions that authorize EPA to forego conducting a separate reasonable progress analysis or that authorize a reasonable progress alternative program comparable to a BART alternative.

Response: As discussed in Section III.A.2 above, we are not finalizing a position that the Texas SO_2 Trading Program is designed to meet reasonable progress requirements. While the program will contribute to meeting Texas' reasonable progress requirements, the necessary analysis, and potentially, emission controls, to fully address reasonable progress for Texas will take place in a separate, future action.

J. Coleto Creek

Comment: We received comments in support of our proposed removal of the special provisions in the Supplemental Allowance Pool for Coleto Creek.[175] We also received a comment stating that the Supplemental Allowance Pool's treatment of Coleto Creek is unlawful, arbitrary, and capricious because this provision would allow SO_2 emissions to increase over time. Under § 97.912(a)(3)(i), if Coleto Creek requires more allowances to be in compliance, those allowances will be provided up to the amount held in the Supplemental Allowance Pool. Because that pool's starting balance is 10,000 tons and given that Coleto Creek's 2016 SO_2 emissions totaled 8,231 tons, § 97.912(a)(3)(i) would allow this unit to more than double its 2016 SO_2 emissions. Nothing in the Texas SO_2 Trading Program would prevent Coleto Creek from increasing its SO_2 emissions to even higher levels, if and when the Supplemental Allowance Pool has accumulated allowances in excess of 10,000 tons.

[175] We note that TCEQ commented in support of removing the special provisions for Coleto Creek but suggested that implementing changes to the program is a potential concern given that the program began in January 2019. TCEQ encourages the EPA to discuss with program stakeholders appropriate timing for making a change to the Supplemental Allowance Pool. Our final rule sets the effective date of the rule changes for program year 2021.

The commenter further asserts that because Vistra and Dynegy have merged, the rationale for having special provisions for Coleto Creek are longer true, with the combined Dynegy-Vistra company owning several units other than Coleto Creek covered by the Texas SO_2 Trading Program. Given that the factual basis for this provision concerning Coleto Creek is no longer true, the commenter suggests that EPA must eliminate 40 CFR 97.912(a)(3)(i).

We also received comments suggesting that we should eliminate the additional flexibility afforded to Coleto Creek's owner in the Supplemental Allowance Pool of the SO_2 trading program FIP because Coleto Creek is no longer an isolated unit in the program. Given the recent merger between Dynegy and Vistra Energy, which owns or operates several other Texas EGUs that are subject to the Texas intrastate trading program for SO_2, Coleto Creek will now be part of a larger set of participating units under the same owner/operator. Because Coleto Creek is no longer at a disadvantage as it was before, the flexibility afforded to Coleto Creek under the Supplemental Allowance Pool is no longer necessary. Vistra Energy will be able to transfer allowances among the multiple participating units should any one source require additional allowances during any control period greater than its allocation, including Coleto Creek. Eliminating the flexibility directly afforded to Coleto Creek under 40 CFR 97.912(a)(3) as a result of the merger will provide an equal opportunity among the participating sources for access to the Supplemental Allowance Pool.

Response: When we finalized our Texas SO_2 Trading Program FIP in October 2017, all sources required to participate in the trading program had the flexibility to transfer allowances among multiple participating units under the same owner/operator when planning operations, with the exception of Coleto Creek, which consists of only one coal-fired unit, and at the time of our October 2017 FIP, this was the only coal-fired unit in Texas owned and operated by Dynegy. In light of this, in our October 2017 FIP, we provided Coleto Creek with additional flexibility by allocating its maximum supplemental allocation from the Supplemental Allowance Pool as long as there were sufficient allowances in the Supplemental Allowance Pool available for allocation, and its actual allocation would not be reduced in proportion with any reductions made to the supplemental allocations to other sources. In our August 2018 proposal, we noted that Dynegy had merged with Vistra, which owns other units that are subject to the trading program. In the August 2018 proposal, we solicited comment on eliminating this additional flexibility for Coleto Creek in light of the recent change in ownership, and we received no adverse comments on such a change. Therefore, on November 14, 2019, we published a supplemental notice of proposed rulemaking that proposed to make this change to the regulations.[176] After considering all comments we received on our supplemental proposal, we are finalizing the removal of the special provisions for Coleto Creek, thus making moot the comments concerning Coleto Creek's treatment under the Supplemental Allowance Pool.

We disagree with the commenter's additional statements that, aside from the treatment of Coleto Creek just discussed, the Supplemental Allowance Pool is arbitrary and capricious because it would allow emissions to increase over time. We have responded elsewhere to the commenter's similar assertion that the Supplemental Allowance Pool would ''inflate the cap'' in sections IV.A and IV.K of this final action.

Comment: We also received comments from AEP, NRG Texas, SPS, and Vistra that side with eliminating the additional flexibility to Coleto Creek due to the recent change in ownership. The additional flexibility would give Coleto Creek priority for allocations from the Supplemental Allowance Pool. AEP states that retaining this flexibility would place Coleto Creek and its owner in a favorable position in comparison to other utilities operating in the ERCOT, which would unfairly impact other EGUs. NRG Texas similarly states this additional flexibility would significantly reduce the allowances available to other sources. SPS explains that eliminating the additional flexibility will ensure a more equitable distribution of allowances for EGUs needing compliance assistance. Vistra submitted comments on both the August 2018 proposal and the November 2019 supplemental proposal in support of eliminating the priority given in the October 2017 final rule to Coleto Creek for allocations from the Supplemental Allowance Pool given that this priority is no longer necessary in light of the facility's change in ownership.

Response: As explained elsewhere in this document, in our August 2018 proposal, we solicited comment on eliminating the additional flexibility for Coleto Creek in light of the recent change in ownership, and we received no adverse comments on such a change. Thereafter, on November 14, 2019, we published a supplemental notice of proposed rulemaking that proposed to make this change to the regulations.[177] After considering all comments we received, we are finalizing the removal of the special provisions for Coleto Creek, thus addressing the comments concerning Coleto Creek's treatment under the Supplemental Allowance Pool.

K. Assurance Provisions and the Variability Limit

Comment: One commenter asserted that EPA's proposed assurance provisions are arbitrary and capricious. Assurance levels, like those established in CSAPR, are designed to account for year-to-year variability in each state's EGU emissions. EPA concluded that these emissions could vary from year to year due to normal fluctuations in electricity demand, weather, economic considerations, etc., and in an interstate trading program, state-level budgets would not necessarily ensure emissions outcomes commensurate with each state's good neighbor obligations. To address this issue, EPA added ''variability limits'', which provide additional headroom in the states' budgets. In CSAPR, these variability limits were based on the maximum historical percentage coal usage (heat input) variability during 2000–2010 experienced by any CSAPR state. The state budget plus the variability limit equals the ''state assurance level.'' [178]

The commenter asserted that EPA states that the addition of an assurance limit was the result of comments that EPA's Texas SO_2 Trading Program would (1) not provide any regulatory pressure on EGUs to reduce their emissions and would actually allow emissions to increase, and (2) would undermine the stringency of the program based on the availability of supplemental allowances, the issuance of allocations to already-retired units, the general method of allocating allowances, and the availability of unlimited allowance banking.[179] The commenter asserted that to address these concerns, EPA proposed to add an assurance level using the same methodology the agency used in CSAPR. EPA claims, ''to the extent that commenters claimed the program would be inadequately stringent due to the allowance allocation methodology, including allocations to retired units, or

[176] 84 FR 61850.

[177] 84 FR 61850.

[178] *See generally* 76 FR 42866 (July 19, 2011).

[179] 84 FR at 61852.

due to the Supplemental Allowance Pool or allowance banking, these concerns are effectively rendered moot by the addition of the assurance level.'' [180] The commenter contends, however, that a cap on the Texas SO_2 Trading Program does not mitigate the errors concerning EPA's rules governing its Supplemental Allowance Pool, banking, and related issues. Were that the case, EPA could simply promulgate any trading program rule it desired, using any reasoning or allocation methodology, as long as the end result equaled some desired total emissions goal.

The commenter further asserts that none of the references pointing to the CSAPR Update Final Rule to support the notion that allocations to retired units and the availability of banking are important to ensure market stability provide any rationale or support for allocating emission credits to already retired EGUs. Allocating allowances to already retired units only serves to inflate the SO_2 budget, thereby reducing the value of the allowances, which disincentivizes SO_2 reduction. Moreover, the commenter asserts that the Texas SO_2 Trading Program arbitrarily creates a windfall to operators that have independently chosen to cease operations or relinquish their permit rights to emit any pollution. Giving permanently-retired sources and their operators a free pass to emit more haze-causing pollution than they are legally allowed to emit under the Clean Air Act cannot comply with the Regional Haze Rule's requirement that any trading program ''achieve greater reasonable progress'' than source-specific BART. 40 CFR 51.308(e), (e)(2); see also 40 CFR 51.308(d)(vi). In a comment submitted following the supplemental proposal adding an assurance level to the Texas SO_2 Trading Program, the commenter further emphasized that the agency proposed to give the owners of those already-retired sources an even bigger emissions ''variability'' cushion, effectively ensuring that those companies will have no incentive or need to reduce emissions at any other source. The commenter goes further stating that the assurance level and variability limit virtually ensure that certain utilities holding emission credits for already-retired sources will be allowed to continue polluting at the same or greater levels than before.

Response: As an initial matter, this action does not reopen any aspect of the CSAPR regulations. However, in order to facilitate our response to comments on the proposed amendments to the Texas SO_2 Trading Program, we first respond to the commenter's statements concerning the CSAPR programs as necessary to correct errors in the commenter's statements that may also implicate the commenter's statements concerning the Texas SO_2 Trading Program. Contrary to the commenter's statements, the CSAPR variability limits do not ''provide headroom in'' or otherwise alter the CSAPR state budgets, which are fixed amounts for all years from 2017 forward. Rather, a state's CSAPR variability limit is a defined increment by which the state's total emissions in a given year may exceed the underlying fixed CSAPR state budget before any incremental emissions trigger requirements to surrender more than one allowance per ton of emissions. Also, the amounts of the CSAPR variability limits were determined based on an analysis of historical variability in states' consumption of all fossil fuels for electricity generation, not states' consumption of only coal for electricity generation.

Turning to the substance of these comments, we continue to believe that the addition of assurance provisions to the Texas SO_2 Trading Program will provide further support for our determination that the Texas SO_2 Trading Program is at least as stringent as the CSAPR SO_2 trading program as applied to Texas and for that reason is sufficiently stringent to meet the requirements for a BART alternative under 40 CFR 51.308(e)(2). When promulgating the Texas SO_2 Trading Program, we found that the average annual emissions authorized by the program's design would be similar to the emissions authorized under CSAPR and well below the 317,100 tons-per-year benchmark established by the sensitivity analysis performed in the 2012 ''CSAPR Better-than-BART'' rulemaking. In the supplemental proposal for this action, in response to comments raising concerns that the program as originally promulgated in fact might not constrain emissions in individual years as effectively as CSAPR, we reiterated these conclusions regarding the program's average annual emissions but also acknowledged that the program's design might not constrain emissions in individual years as effectively as CSAPR because of the lack of provisions comparable to CSAPR's ''assurance provisions.'' We therefore proposed and in this action are now finalizing the addition of assurance provisions to the Texas SO_2 Trading Program in order to further ensure that the program's design is at least as stringent as the CSAPR SO_2 program as applied to Texas, not only on an average annual basis but also in individual years.

The commenter suggests that even where revisions to a trading program have been specifically designed to achieve a desired total emissions goal—in this instance, ensuring that statewide emissions levels in individual years do not exceed the 317,100 tons-per-year benchmark—the ability of the revisions to in fact achieve that goal is not the relevant criterion by which we should evaluate the appropriateness of the revisions, and that we should instead evaluate the revisions (and the program as a whole) based on whether or not the revised program also addresses other concerns raised by the commenter. We disagree with this suggestion. In noting the list of program design features that the commenter considers problematic, we did not endorse the full set of concerns that the commenter asserts these design features raise. Rather, we acknowledged the specific concern as to whether the program is or is not at least as stringent in individual years as the CSAPR SO_2 trading program, and we proposed amendments to address that specific concern. While the commenter asserts that the identified design features raise additional concerns and believes that we should evaluate the program according to different criteria, we do not agree. We have addressed the commenter's assertions regarding the identified design features and additional evaluation criteria in response to other comments. In general, the commenter provides no cogent explanation why the addition of an assurance level (which effectively functions as a ''cap'' as their own language concedes) would not ensure emissions performance of the program on an annual basis below that level. Nor has the commenter explained why, if that is the case, the other objections they raise with respect to allocations or banking of allowances are of relevance to EPA's determination that the program achieves the necessary level of stringency for a BART alternative under 51.308(e)(2).

The commenter's criticism of the discussion in the supplemental proposal concerning our general rationale for not immediately discontinuing allocations to retired units has no relevance to the proposed addition of assurance provisions to the Texas SO_2 Trading Program or any of the other proposed amendments in the supplemental proposal. We have addressed the commenter's assertions regarding the permissibility of allocating allowances

[180] 84 FR at 61854.

to retired units in response to other comments.

Comment: One commenter asserts that EPA's calculation of its proposed variability limit uses out-of-date data, rather than the most recent data as used in CSAPR. In promulgating CSAPR, EPA's original stated reasoning for the need for a variability limit was to account for ''weather, economic activity, the portion of electric generation that is fossil fuel fired, and the length and number of outages at power generation units, which vary over time.'' [181] The commenter asserts that in its supplemental proposal for its Texas SO_2 Trading Program, EPA simply adopts the variability for Texas (7%) that was calculated in the CSAPR rulemaking, instead of updating it to account for more recent data and the units that are actually participating in the Texas SO_2 Trading Program. The CSAPR heat input data from 2000–2010 are now eight years out of date. Thus, this data set is no longer suitable for its originally intended purpose—to account for variations in weather, economic activity, etc., that influence electricity generation.

The commenter asserts that EPA must, at a minimum, update the technical analysis underlying its variability limits, as the agency has done in other contexts, such as its recent update to CSAPR, for example, where EPA relied on updated Integrated Planning Model data to analyze the impact of the updated Transport Rule on the U.S. electric power sector, as well as its preliminary transport modeling data for the 2015 ozone NAAQS. In so doing, EPA recognized the many changes to the distribution and magnitude of electric sector emissions, including the significant expansion of renewable energy generation resources, recent EGU retirements and control additions, changes in the cost and efficacy of pollution control technologies, reductions in electricity demand, electric system transmission changes, and persistently low natural gas prices.[182] In the supplemental proposal for its Texas SO_2 Trading Program, EPA arbitrarily fails to acknowledge—let alone address—the numerous changes to the electric sector since the agency adopted its CSAPR variability limits in 2011.[183]

The commenter states that in addition, the obsoleteness of the heat input data aside, given the EGU retirements that have occurred since 2010, that data set is much different than what would be calculated based on the units that would actually participate in EPA's Texas SO_2 Trading Program. The commenter purported to illustrate this via a table comparing historical heat inputs from 2000–2010 for units under original CSAPR, units in the Texas trading program, and units in the Texas program minus retired units. Comparing the columns showing these heat inputs, commenter asserts that the magnitudes of the data sets indicate that despite being of the same years, they are composed of different units. In fact, the heat input data set composed of only the unretired units that would actually participate in the Texas SO_2 trading program is approximately one third the size of the data set that EPA is basing its variability analysis on. In its continued strained attempt to justify its inadequate Texas SO_2 trading program by comparison to CSAPR, commenter claims EPA ignores its earlier decision to base its variability calculation on only the units that actually participate in the trading program.

Response: In the supplemental proposal, we proposed to adopt a variability limit of 7% for the Texas SO_2 Trading Program, where the proposed limit was calculated based on the annual heat input values for Texas in the same overall data set used to calculate the analogous variability limit of 18% for the CSAPR SO_2 program. In most respects, the Texas SO_2 Trading Program has been designed to replicate relevant aspects of the CSAPR SO_2 program. We do not dispute that the Texas electricity sector has evolved in the years since the CSAPR rulemaking and we agree with the general principle that the most current data of sufficient quality and representativeness should be used when conducting new rulemaking activities. However, we do not believe that acceptance of the general principle in favor of using more recent data when available necessarily requires that the principle be applied to every detail of a rulemaking, such as this one, that is being conducted with an overall purpose of closely replicating the structure of a previous rulemaking.

Nevertheless, in order to assess the potential impacts of using more recent data instead of the CSAPR rulemaking data set specifically for purposes of establishing the amount of the variability limit for the Texas SO_2 Trading Program, we have calculated what the variability limit would be if it were calculated using the more recent data set suggested by the commenter. In the following comment, the commenter states that this calculation would result in a variability limit of 2%, but as discussed in greater detail in our response to that comment, the commenter did not actually use the more recent data set and furthermore made a material error in the calculation procedure. When the calculation procedure is applied to the more recent data set and the procedural error is corrected, the result would be a higher variability limit than we proposed—specifically, 12% instead of 7%. Because neither this commenter nor any other commenter advocates using a variability limit higher than 7%, and some other commenters specifically support use of the variability limit and resulting assurance level calculated based on values for Texas in the data set used in the CSAPR rulemaking, we do not find it necessary to use an updated data set in this instance.

Comment: We received a comment that disagreed with the computational methodology EPA used to calculate the variability limit of 7%, arguing that the limit should instead be 2%. The commenter purported to recalculate what a Texas SO_2 Trading Program variability limit would be if it were based on EPA's original methodology used in CSAPR. The commenter purported to follow the CSAPR methodology and use up-to-date data and include *only* those units that are expected to be covered by the program.

Response: In this proceeding, we did not seek comment on or reopen any aspect of the CSAPR regulations. However, in order to facilitate our response to comments on the proposed amendments to the Texas SO_2 Trading Program, we are responding to the commenter's statements concerning the CSAPR programs as necessary to correct errors in the commenter's statements that may also implicate the commenter's statements concerning the Texas SO_2 Trading Program.

[181] *See* 76 FR 48,208, 48,265 (Aug. 8, 2011). EPA specifically notes that the factors that contribute to power sector variability change with time. Also, note that EPA updated its previous variability calculations, based on 2002–2008, in part to utilize the more recent data available to it. EPA should have taken the same approach in its supplemental proposal.

[182] *See generally* Ex. 1, EPA, ''Documentation for EPA's Power Sector Modeling Platform v6—November 2018 Reference Case,'' available at *https://www.epa.gov/airmarkets/documentation-epas-power-sector-modeling-platform-v6-november-2018-reference-case.*

[183] *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (''The agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' ''); *Sierra Club* v. *EPA,* 671 F.3d 955, 967 (9th Cir. 2012) (''[I]f new information indicates to EPA that [a proposed rule] awaiting approval is inaccurate or not current, . . . EPA should properly evaluate the new information and may not simply ignore it without reasoned explanation of its choice.'').

We disagree with the commenter's assertions that we made an error in the statistical procedure for calculating the variability limits used in the CSAPR trading programs and the variability limit proposed for the Texas SO_2 Trading Program. In fact, the commenter made a mistake in the calculation of the variability limits. We have added to the docket for this action a spreadsheet that is a modified version of the spreadsheet the commenter submitted to the docket as Exhibit 3 to the comments on the supplemental proposal.[184] See the spreadsheet and the Response to Comments document found in the docket associated with this final action for a detailed explanation of the calculation and discussion of how correction of one of the values in the spreadsheet submitted by the commenter yields values that confirm the correctness of our calculations.

The results of the calculations in this section confirm a CSAPR SO_2 variability limit of 18%. The CSAPR SO_2 5% variability limit asserted by the commenter results only from using the incorrect value of 11 for the ''size'' variable in the CONFIDENCE function.

Comment: We received a comment stating that EPA's proposed assurance level is incorrect because the assurance level EPA borrows from CSAPR is simply the sum of the SO_2 budget and the variability limit. Because the EPA incorrectly incorporated the Texas variability limit from CSAPR into its Texas SO_2 trading program, and because EPA's trading budget of 238,393 tons itself is based on out-of-date and inappropriate data, consequently, EPA's calculation of its variability limit, which is simply a percentage of this budget, is flawed. The commenter argues that had EPA re-applied the original CSAPR allocation methodology using updated information, and removed retired units, it would have discovered that the individual allocations in many instances would have changed significantly and the overall budget would have been reduced significantly. The commenter asserts that the trading budget would have been reduced from 238,393 tons to 176,332 tons. This represents a decrease of 62,061 tons or an approximately 26% change. Adding a 2% variability to the revised trading budget of 176,332 tons would result in an assurance limit of 179,859 tons.

Furthermore, the commenter asserts that even at this lower emissions level, the Texas SO_2 Trading Program will not serve to place any regulatory pressure on Texas SO_2 sources to reduce their emissions because the 2018 SO_2 emissions of the participating non-retired units—which should be the only units participating in the program—total 157,119 tons. These emissions are already below the reduced assurance limit of 179,859 tons commenter calculated above.

Finally, the commenter states that because the Texas SO_2 Trading Program does not provide for a declining cap over time, in comparison to actual source-by-source BART, even if corrected to remove retired units it merely preserves the status quo. As such, it violates the primary objective of the national goal of the visibility program, which is ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution.''

Response: We disagree with this comment. The commenter correctly notes that the proposed assurance level for the Texas SO_2 Trading Program is derived from the proposed 7% variability limit and the existing budget for the Texas SO_2 Trading Program. Based on the commenter's beliefs that the variability limit should be 2% and that the existing budget is unlawfully high, the commenter asserts that the proposed assurance level is consequently also too high. We disagree both that the variability limit should be 2% and that the existing budget is unlawfully high. Accordingly, we also disagree with the commenter's resulting assertion that the proposed assurance level is too high. We have addressed the commenter's assertions regarding the proposed variability limit in response to other comments. As indicated in those responses, we continue to believe that 7% is an appropriate value to establish as the variability limit for the Texas SO_2 Trading Program. Likewise, we have also addressed the commenter's assertions regarding the lawfulness of the existing budget for the Texas SO_2 Trading Program in response to other comments, and the commenter offers no new criticism of the existing budget that was not already raised in those previous comments and addressed in our responses to those comments.

L. Venue

Comment: We received a comment asserting that if EPA retains the intrastate trading program, the agency must publish a finding that the Texas SO_2 Trading Program ''is based on a determination of nationwide scope or effect.'' 42 U.S.C. 7607(b)(1). The commenter asserted that such a finding is necessary because the Texas SO_2 Trading Program is plainly based on such a determination and should be reviewed in the United States Court of Appeals for the District of Columbia. The commenter claimed that this is for two reasons. First, in comparing the Texas SO_2 Trading Program to the Better-than-BART rule to satisfy the requirements of 40 CFR 51.308(e), EPA reinterpreted an established and nationally applicable law. Second, the commenter claimed that EPA's unlawful interpretation of 40 CFR 51.308(e) amounts to a revision of a nationally applicable regulation. The commenter noted that in this comment, the commenter does not challenge CSAPR itself or EPA's CSAPR Better-than-BART determination, but is instead asserting that the Texas SO_2 Trading Program is based on those rules, which are nationally applicable and contain determinations of nationwide scope and effect. The commenter asserted that even if EPA does not publish a finding that the Texas SO_2 Trading Program is based on a determination of nationwide scope or effect (and does not withdraw the FIP promulgating the Texas SO_2 Trading Program), subsequent legal challenges will still be properly venued in the D.C. Circuit pursuant to 42 U.S.C. 7607(b)(1).

Response: To the extent commenter is asserting that this action is ''nationally applicable'' for purposes of section 307(b), that claim is clearly incorrect. As the D.C. Circuit has recently explained, ''[t]he court need look only to the face of the agency action, not its practical effects, to determine whether an action is nationally applicable.''[185] On its face, this action is locally applicable because it applies in only a single state, Texas. This action has immediate, legal effect only for certain sources within Texas. Furthermore, EPA is not adopting a new interpretation of its regulations at 40 CFR 51.308(e)(2); nor is it correct to characterize EPA's application of those regulations as a revision necessitating national rulemaking.

EPA also disagrees that this action must be challenged in the D.C. Circuit under the ''nationwide scope or effect'' portion of the venue provision of CAA section 307(b). In general under section 307(b), an EPA action ''which is locally or regionally applicable'' may be filed ''*only* in the United States Court of

[184] See ''EPA modified version of commenters Ex_3_-_Recalculate_TX_SO_2_Trading _Variability.xlsx,'' available in the docket for this action.

[185] *Sierra Club* v. *EPA,* 926 F.3d 844, 849 (D.C. Cir. 2019) (citing *Dalton Trucking,* 808 F.3d 875, 881 (D.C. Cir. 2015) and *Am. Road & Transp. Builders Ass'n* v. *EPA,* 705 F.3d 453, 456 (D.C. Cir. 2013)).

Appeals'' covering that area.[186] The only exception to this mandate is where the Administrator expressly finds that the locally or regionally applicable action is based on a determination of nationwide scope or effect and publishes such a finding. The requirement that the Administrator find and publish that an otherwise locally or regionally applicable action is based on a determination of nationwide scope or effect is an express statutory requirement for application of this venue exception; this exception is not being invoked by EPA in this action. EPA has made no finding in this action and is not publishing any finding that this action is based on a determination of nationwide scope or effect. The absence of either such a finding or publication of such a finding makes this venue exception in CAA section 307(b) inapplicable. Absent an express statement—and publication—that such a finding has been made, thus invoking the venue exception, there can be no application of that exception.[187] CAA section 307 expressly provides the Agency full discretion to make its own determination of whether to invoke the exception in the Congressionally-dictated venue provision.[188]

Even assuming that a court could review the lack of such a finding, and lack of publication of such a finding, under the arbitrary and capricious standard,[189] the EPA's decision not to do so is not unreasonable in this case. As an initial matter, this action does not apply to any sources other than those covered by the program in the State of Texas. By the same token, the applicability of the action does not span multiple federal judicial circuits. Further, EPA is not proposing or adopting a new or different interpretation of its regulations at 40 CFR 51.308(e)(2), nor is it correct to characterize EPA's application of those regulations as a revision necessitating national rulemaking. The commenter's characterization of EPA's analysis as conducting a novel comparison of the Texas program to CSAPR as a BART alternative is incorrect. In the final action, EPA is making no such interpretation that 51.308(e)(2) authorizes a comparison between two BART alternatives. Rather, in this final action, EPA has determined it is acceptable to continue to rely on the CSAPR-Better-than-BART analysis (which included Texas) under the unique, state-specific circumstances presented here: That the intrastate trading program in Texas achieves the same or better emissions outcomes as the CSAPR program would have. The CSAPR Better-than-BART analysis on which EPA is relying uses presumptive BART limits—in compliance with 51.308(e)(2)(i)(C)—to demonstrate greater reasonable progress.

Further, the *application* of the nationally applicable 2012 and 2017 CSAPR findings in Texas is a ''locally or regionally applicable'' action; that application does not in itself make the lack of EPA invoking the exception unreasonable. While the 2012 finding was appropriately reviewed (and upheld) in the D.C. Circuit, and the 2017 finding is currently being reviewed in the D.C. Circuit, *see NPCA* v. *EPA,* 17–1253 (D.C. Cir.), the *application* of those findings in Texas is merely one aspect of this ''locally or regionally applicable'' action. In any future action that may raise similar circumstances as Texas (and EPA is aware of no such situation at this time), EPA's determination whether to promulgate an intrastate trading program as a BART alternative would be based on a record and analysis specific to the sources in that state at that time. EPA has announced no national policy or interpretation that the decisions in this action are, or would necessarily be, applicable in any future action. Thus, EPA has not reinterpreted or revised its Regional Haze Rule regulations in this action, and it is inaccurate to characterize the mere application of regulations in a case-specific circumstance as a revision of those regulations. Under such circumstances, EPA's lack of a finding or publication of such a finding here is hardly unreasonable.

Finally, we note that EPA did not make a finding in the October 17, 2017 final action originally promulgating the Texas SO_2 Trading Program that such action was based on a determination of nationwide scope or effect. This action merely affirms the 2017 action with certain amendments. Petitioners seeking judicial review of that action correctly filed for review in the Fifth Circuit, *see NPCA* v. *EPA,* No. 17–60828 (5th Cir.), and that case is being held in abeyance pending the completion of this action. No petitions for review of the original FIP action were filed in the D.C. Circuit, nor would it have been appropriate to do so.

M. Other

Comment: One commenter, while appreciative of the revisions made to the program by the EPA, expressed concern that without decreasing emissions assurance limitations or source-specific SO_2 limits, improved visibility in protected areas such as the Wichita Mountains National Wildlife Refuge and Guadalupe Mountains National Park will not come to fruition as a result of more concentrated emissions, even if they come from fewer sources.

The commenter also expressed concern for potential impacts to local air quality. While SO_2 emissions from individual sources may technically meet state-wide air quality targets, there remains a potential to negatively impact local air quality, damaging both visibility and human health. The commenter proposed two potential options that the EPA might consider. The first is to examine historic emissions by source and define new limits on a per-facility basis informed by historic emissions that met CSAPR for SO_2. This would ensure that even if some facilities closed, those that remained operational would not be able to increase their SO_2 emissions. The second suggested option would be to implement emission limits that decline annually. Under a declining emissions-limit scenario, if plants did close, operational facilities would potentially still be able to emit more, but to a lesser extent than if the cap stayed constant. If all regulated facilities stayed open, each polluter would have to find additional methods to decrease SO_2 emissions, further improving visibility and human health.

The commenter also expressed concern in consideration of units not participating in the program and their contribution to the total assurance provisions. The Texas SO_2 Trading Program will allot 35,000 tons per year to non-participating sources, effectively increasing the assurance provision to 290,081 tons per year. While SO_2 emissions in Texas have steadily declined, the Texas SO_2 Trading Program would nearly allow emissions to return to 2014 levels. The commenter asserts that it is nonsensical to place a limit on SO_2 emissions that does not pressure polluters to reduce emissions. Previously discussed comments argue

[186] *See* 42 U.S.C. 7607(b)(1) (emphasis added).

[187] *See, e.g., Lion Oil* v. *EPA,* 792 F.3d 978, 984 n.1 (8th Cir. 2015) (even where EPA, unlike here, made the necessary finding, the court found no need to decide application of the venue exception absent publication of that finding); *Texas* v. *EPA,* 829 F.3d 405, 419 (5th Cir. 2016) (''This finding is an independent, post hoc, conclusion by the agency about the nature of the determinations; the finding is not, itself, the determination.''). *See also Dalton Trucking* v. *EPA,* 808 F.3d 875 (D.C. Cir. 2015).

[188] *See, e.g., Texas* v. *EPA,* 829 F.3d at 419–20 (the venue exception ''gives the Administrator the *discretion* to move venue to the D.C. Circuit by publishing a finding declaring the *Administrator's belief* that the action is based on a determination of nationwide scope or effect.'') (emphasis added).

[189] *Cf. Sierra Club* v. *EPA,* 926 F.3d 844, 850 (D.C. Cir. 2019) (declining to resolve whether failure to make a finding is reviewable but concluding the absence of such a finding was not arbitrary and capricious under the facts of the case).

that unlike source-specific BART control requirements, the Texas SO_2 Trading Program allows for emission to increase compared to recent emission levels. The state of Texas has clearly made great strides in decreasing sulfur emissions from coal-fired powerplants and the EPA has a responsibility to Texans and residents of neighboring states to maintain that progress, not reverse it.

Response: We appreciate the commenter's concerns and suggestions. With regards to localized impacts, as previously discussed in response to other comments, the analysis EPA is relying on does not show visibility declines compared to the baseline in any Class I area under the BART alternative. Under the Regional Haze Rule, states are directed to conduct BART determinations for ''BART-eligible'' sources that may be anticipated to cause or contribute to any visibility impairment in a Class I area. States are required to identify the level of control representing BART after considering the five statutory factors set out in section 169A(g)(2) for each source subject-to-BART.[190] However, the Regional Haze Rule also gives states the flexibility to adopt an emissions trading program or alternative program in place of requiring source-specific BART controls, as long as the alternative provides greater reasonable progress towards improving visibility than BART. As discussed in section I.A. of this final action, 40 CFR 51.308(e)(2) specifies how a state must conduct the demonstration to show that an alternative program will achieve greater reasonable progress than the installation and operation of BART. As discussed in section III.A.2, we are taking final action to affirm our determination that the Texas SO_2 Trading Program, as amended in this final action, meets the requirements of 40 CFR 51.308(e)(2) as a BART alternative for SO_2 to satisfy Texas' Regional Haze obligations. Comments on EPA's decision to authorize alternative measures, including emissions trading programs, in the original 1999 Regional Haze Rule are beyond the scope of this action.

The comment that we have ''allotted'' 35,000 tons to non-participating units is incorrect. The Texas SO_2 Trading Program only pertains to the particular set of EGUs specified in Table 1 of this final rule. The estimate of emissions from non-participating units is used as a conservative assumption to allow for a comparison of SO_2 emissions from EGUs in Texas under the Texas program with emissions under CSAPR.

V. Final Action

A. Regional Haze

We are taking final action to affirm our October 2017 FIP that established the Texas SO_2 intrastate trading program addressing emissions of SO_2 from certain EGUs in Texas as a BART alternative, with certain amendments to the trading program. These amendments consist of (1) the addition of assurance provisions; (2) revisions to the Supplemental Allowance Pool allocation provisions, including amendments to the allocation methodology such that allowance allocations are in proportion to each owner's total emissions in excess of the owner's total base allowance allocations, elimination of the additional flexibility to transfer allowances originally offered under the trading program for Coleto Creek, and reduction in the number of allowances that can be allocated from the Supplemental Allowance Pool in any year to 16,688 tons plus any allowances added to the pool in that year from retired units; (3) termination of the opt-in provisions; and (4) revision of the allowance recordation provisions. We are also correcting a 2-ton error we made in the allowance allocation for El Paso Electric's Newman Plant due to a unit-identification error, thereby increasing the trading program budget from 238,393 tons to 238,395 tons. We are taking final action to affirm our determination that the Texas SO_2 intrastate trading program, as amended in this final rulemaking, satisfies the Regional Haze Rule requirements for BART alternatives at 40 CFR 51.308(e)(2). We are also taking final action to affirm our October 2017 approval of Texas' SIP determination that no Texas sources are subject to BART for PM.

B. Interstate Visibility Transport

We are taking final action to affirm our finding that Texas' participation in CSAPR to satisfy NO_X BART and our SO_2 intrastate trading program, as amended in this final rulemaking, fully address Texas' interstate visibility transport obligations for the following six NAAQS: (1) 1997 8-hour ozone; (2) 1997 $PM_{2.5}$ (annual and 24 hour); (3) 2006 $PM_{2.5}$ (24-hour); (4) 2008 8-hour ozone; (5) 2010 1-hour NO_2; and (6) 2010 1-hour SO_2. Texas' SO_2 emission reductions under the Texas SO_2 intrastate trading program, as amended in today's final rulemaking, are consistent with the level of emission reductions relied upon by other states during Regional Haze consultation, and the intrastate trading program is therefore adequate to ensure that emissions from Texas do not interfere with measures to protect visibility in nearby states in accordance with CAA section 110(a)(2)(D)(i)(II).

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

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

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

C. Paperwork Reduction Act

This action does not impose any new information collection burden under the PRA. The Office of Management and Budget (OMB) has previously approved the information collection activities contained in the existing Texas SO_2 Trading Program regulations as part of the most recent information collection request (ICR) renewal for the CSAPR trading programs and has assigned OMB control number 2060–0667. The revisions approved in this action do not alter the information collection activities contained in the existing regulations.

D. Regulatory Flexibility Act

I certify that this action will not have a significant impact on a substantial number of small entities. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This rule does not impose any requirements or

[190] The State must take into consideration the five statutory factors: (1) The costs of compliance, (2) the energy and non-air quality environmental impacts of compliance, (3) any existing control technology in use at the source, (4) the remaining useful life of the source, and (5) the degree of visibility improvement which may reasonably be anticipated to result.

create impacts on small entities. This FIP action under Section 110 of the CAA will not create any new requirement with which small entities must comply. Accordingly, it affords no opportunity for the EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. We have therefore concluded that, this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

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

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

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

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

Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks [191] applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. EPA interprets E.O. 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under Section 5–501 of the E.O. has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action is not subject to E.O. 13045 because it implements specific standards established by Congress in statutes. However, to the extent this rule will limit emissions of SO_2, the rule will have a beneficial effect on children's health by reducing air pollution.

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

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). We have determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The rule limits emissions of SO_2 from certain facilities in Texas.

L. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability.

List of Subjects in 40 CFR Part 97

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Nitrogen dioxide, Reporting and recordkeeping requirements, Sulfur oxides.

Andrew Wheeler,
Administrator.

For the reasons stated in the preamble, part 97 of chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 97—FEDERAL NO_X BUDGET TRADING PROGRAM, CAIR NO_X AND SO_2 TRADING PROGRAMS, CSAPR NO_X AND SO_2 TRADING PROGRAMS, AND TEXAS SO_2 TRADING PROGRAM

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

Authority: 42 U.S.C. 7401, 7403, 7410, 7426, 7491, 7601, and 7651, *et seq.*

Subpart FFFFF—TEXAS SO_2 TRADING PROGRAM

■ 2. Amend § 97.902 by:
■ a. In the definitions of ''Acid Rain Program'', ''Allowance Management System'', and ''Allowance Management System account'', capitalizing the first three words;
■ b. Adding in alphabetical order a definition of ''Assurance account'';
■ c. In the definition of ''Authorized account representative'', capitalizing the word ''trading'' the first time it appears;
■ d. Adding in alphabetical order definitions of ''Common designated representative'', ''Common designated representative's assurance level'', and ''Common designated representative's share''; and
■ e. Revising the definitions of ''General account'' and ''Texas SO_2 Trading Program allowance deduction''.

The additions and revisions read as follows:

§ 97.902 Definitions.

* * * * *

Assurance account means an Allowance Management System account, established by the Administrator under § 97.925(b)(3) for certain owners and operators of a group of one or more Texas SO_2 Trading Program sources and units, in which are held Texas SO_2 Trading Program allowances available for use for a control period in a given year in complying with the Texas SO_2 Trading Program assurance provisions in accordance with §§ 97.906 and 97.925.

* * * * *

Common designated representative means, with regard to a control period in a given year, a designated representative where, as of April 1 immediately after the allowance transfer deadline for such control period, the same natural person is authorized under §§ 97.913(a) and 97.915(a) as the designated representative for a group of one or more Texas SO_2 Trading Program sources and units.

Common designated representative's assurance level means, with regard to a specific common designated representative and control period in a given year for which the State assurance

[191] 62 FR 19885 (Apr. 23, 1997).

level is exceeded as described in § 97.906(c)(2)(iii):

(1) The amount (rounded to the nearest allowance) equal to the sum of the total amount of Texas SO_2 Trading Program allowances allocated for such control period under § 97.911, or deemed to have been allocated under paragraph (2) of this definition, to the group of one or more Texas SO_2 Trading Program units having the common designated representative for such control period multiplied by the sum for such control period of the Texas SO_2 Trading Program budget under § 97.910(a)(1) and the variability limit under § 97.910(b) and divided by the sum of the total amount of Texas SO_2 Trading Program allowances allocated for such control period under § 97.911, or deemed to have been allocated under paragraph (2) of this definition, to all Texas SO_2 Trading Program units;

(2) Provided that, in the case of a Texas SO_2 Trading Program unit that operates during, but has no amount of Texas SO_2 Trading Program allowances allocated under § 97.911 for, such control period, the unit shall be treated, solely for purposes of this definition, as being allocated the amount of Texas SO_2 Trading Program allowances shown for the unit in § 97.911(a)(1).

Common designated representative's share means, with regard to a specific common designated representative for a control period in a given year and the total amount of SO_2 emissions from all Texas SO_2 Trading Program units during such control period, the total tonnage of SO_2 emissions during such control period from the group of one or more Texas SO_2 Trading Program units having the common designated representative for such control period.

* * * * *

General account means an Allowance Management System account, established under this subpart, that is not a compliance account or an assurance account.

* * * * *

Texas SO_2 Trading Program allowance deduction or *deduct Texas SO_2 Trading Program allowances* means the permanent withdrawal of Texas SO_2 Trading Program allowances by the Administrator from a compliance account (*e. g.,* in order to account for compliance with the Texas SO_2 Trading Program emissions limitation) or from an assurance account (*e. g.,* in order to account for compliance with the assurance provisions under §§ 97.906 and 97.925).

* * * * *

§ 97.904 [Amended]

■ 3. Amend § 97.904 by removing and reserving paragraph (b).

■ 4. Amend § 97.906 by:

■ a. In paragraph (b)(2), adding the words ''and assurance provisions'' after the words ''emissions limitation'';

■ b. Redesignating paragraphs (c)(2) through (6) as paragraphs (c)(3) through (7) and adding a new paragraph (c)(2);

■ c. Revising newly redesignated paragraph (c)(3); and

■ d. In newly redesignated paragraph (c)(4)(ii), removing the text ''paragraph (c)(1)(ii)(A)'' and adding in its place the text ''paragraphs (c)(1)(ii)(A) and (c)(2)(i) through (iii)''.

The additions and revision read as follows:

§ 97.906 General provisions.

* * * * *

(c) * * *

(2) *Texas SO_2 Trading Program assurance provisions.* (i) If total SO_2 emissions during a control period in a given year from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources exceed the State assurance level, then the owners and operators of such sources and units in each group of one or more sources and units having a common designated representative for such control period, where the common designated representative's share of such SO_2 emissions during such control period exceeds the common designated representative's assurance level for such control period, shall hold (in the assurance account established for the owners and operators of such group) Texas SO_2 Trading Program allowances available for deduction for such control period under § 97.925(a) in an amount equal to two times the product (rounded to the nearest whole number), as determined by the Administrator in accordance with § 97.925(b), of multiplying—

(A) The quotient of the amount by which the common designated representative's share of such SO_2 emissions exceeds the common designated representative's assurance level divided by the sum of the amounts, determined for all common designated representatives for such sources and units for such control period, by which each common designated representative's share of such SO_2 emissions exceeds the respective common designated representative's assurance level; and

(B) The amount by which total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources for such control period exceed the State assurance level.

(ii) The owners and operators shall hold the Texas SO_2 Trading Program allowances required under paragraph (c)(2)(i) of this section, as of midnight of November 1 (if it is a business day), or midnight of the first business day thereafter (if November 1 is not a business day), immediately after the year of such control period.

(iii) Total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources during a control period in a given year exceed the State assurance level if such total SO_2 emissions exceed the sum, for such control period, of the Texas SO_2 Trading Program budget under § 97.910(a)(1) and the variability limit under § 97.910(b).

(iv) It shall not be a violation of this subpart or of the Clean Air Act if total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources during a control period exceed the State assurance level or if a common designated representative's share of total SO_2 emissions from the Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources during a control period exceeds the common designated representative's assurance level.

(v) To the extent the owners and operators fail to hold Texas SO_2 Trading Program allowances for a control period in a given year in accordance with paragraphs (c)(2)(i) through (iii) of this section,

(A) The owners and operators shall pay any fine, penalty, or assessment or comply with any other remedy imposed under the Clean Air Act; and

(B) Each Texas SO_2 Trading Program allowance that the owners and operators fail to hold for such control period in accordance with paragraphs (c)(2)(i) through (iii) of this section and each day of such control period shall constitute a separate violation of this subpart and the Clean Air Act.

(3) *Compliance periods.* (i) A Texas SO_2 Trading Program unit shall be subject to the requirements under paragraph (c)(1) of this section for the control period starting on January 1, 2019 and for each control period thereafter.

(ii) A Texas SO_2 Trading Program unit shall be subject to the requirements under paragraph (c)(2) of this section for the control period starting on January 1, 2021 and for each control period thereafter.

* * * * *

■ 5. Amend § 97.910 by:

■ a. Revising the section heading;

■ b. In paragraph (a)(1), removing ''238,393'' and adding in its place ''238,395''; and

■ c. Adding paragraphs (b) and (c).

The revision and additions read as follows:

§ 97.910 Texas SO_2 Trading Program budget, Supplemental Allowance Pool budget, and variability limit.

* * * * *

(b) The variability limit for the Texas SO_2 Trading Program budget for the control periods in 2021 and thereafter is 16,688 tons.

(c) The Texas SO_2 Trading Program budget in paragraph (a)(1) of this section does not include any tons in the Supplemental Allowance Pool budget in paragraph (a)(2) of this section or the variability limit in paragraph (b) of this section.

■ 6. Amend § 97.911 by:

■ a. Revising paragraph (a)(1);

■ b. In paragraph (a)(2), removing the text ''allocated under the Texas Supplemental Allowance Pool under 40 CFR 97.912.'' and adding in its place the text ''transferred to the Supplemental Allowance Pool for potential allocation in accordance with § 97.912.'';

■ c. Removing and reserving paragraph (b);

■ d. In paragraph (c)(1), removing the text ''paragraph (a) or (b)'' and adding in its place the text ''paragraph (a)''; and

■ e. Revising paragraph (c)(5).

The revisions read as follows:

§ 97.911 Texas SO_2 Trading Program allowance allocations.

(a)(1) Except as provided in paragraph (a)(2) of this section, Texas SO_2 Trading Program allowances from the Texas SO_2 Trading Program budget will be allocated, for the control periods in 2019 and each year thereafter, as provided in Table 1 to this paragraph (a)(1):

TABLE 1 TO PARAGRAPH (a)(1)—TEXAS SO_2 TRADING PROGRAM ALLOCATIONS

Texas SO_2 trading program units	ORIS code	Texas SO_2 trading program allocation (tons)	Affiliated ownership group
Big Brown Unit 1	3497	8,473	Vistra Energy..
Big Brown Unit 2	3497	8,559	Vistra Energy.
Coleto Creek Unit 1	6178	9,057	Vistra Energy.
Fayette (Sam Seymour) Unit 1	6179	7,979	Lower Colorado River Authority/City of Austin.
Fayette (Sam Seymour) Unit 2	6179	8,019	Lower Colorado River Authority/City of Austin.
Graham Unit 2	3490	226	Vistra Energy.
HW Pirkey Unit 1	7902	8,882	American Electric Power.
Harrington Unit 061B	6193	5,361	Xcel Energy.
Harrington Unit 062B	6193	5,255	Xcel Energy.
Harrington Unit 063B	6193	5,055	Xcel Energy.
JT Deely Unit 1	6181	6,170	City of San Antonio.
JT Deely Unit 2	6181	6,082	City of San Antonio.
Limestone Unit 1	298	12,081	NRG Energy.
Limestone Unit 2	298	12,293	NRG Energy.
Martin Lake Unit 1	6146	12,024	Vistra Energy.
Martin Lake Unit 2	6146	11,580	Vistra Energy.
Martin Lake Unit 3	6146	12,236	Vistra Energy.
Monticello Unit 1	6147	8,598	Vistra Energy.
Monticello Unit 2	6147	8,795	Vistra Energy.
Monticello Unit 3	6147	12,216	Vistra Energy.
Newman Unit 2	3456	1	El Paso Electric.
Newman Unit 3	3456	1	El Paso Electric.
Newman Unit **4	3456	2	El Paso Electric.
Newman Unit **5	3456	2	El Paso Electric.
Sandow Unit 4	6648	8,370	Vistra Energy.
Sommers Unit 1	3611	55	City of San Antonio.
Sommers Unit 2	3611	7	City of San Antonio.
Stryker Unit ST2	3504	145	Vistra Energy.
Tolk Unit 171B	6194	6,900	Xcel Energy.
Tolk Unit 172B	6194	7,062	Xcel Energy.
WA Parish Unit WAP4	3470	3	NRG Energy.
WA Parish Unit WAP5	3470	9,580	NRG Energy.
WA Parish Unit WAP6	3470	8,900	NRG Energy.
WA Parish Unit WAP7	3470	7,653	NRG Energy.
Welsh Unit 1	6139	6,496	American Electric Power.
Welsh Unit 2	6139	7,050	American Electric Power.
Welsh Unit 3	6139	7,208	American Electric Power.
Wilkes Unit 1	3478	14	American Electric Power.
Wilkes Unit 2	3478	2	American Electric Power.
Wilkes Unit 3	3478	3	American Electric Power.

* * * * *

(c) * * *

(5) With regard to the Texas SO_2 Trading Program allowances that are not recorded, or that are deducted as an incorrect allocation, in accordance with paragraphs (c)(2) and (3) of this section, the Administrator will transfer such Texas SO_2 Trading Program allowances to the Supplemental Allowance Pool for potential allocation in accordance with § 97.912.

■ 7. Amend § 97.912 by:

■ a. In paragraph (a) introductory text, removing the text ''each control period in 2019 and thereafter,'' and adding in its place the text ''the control periods in 2019 and 2020,'';

■ b. In paragraph (a)(1), removing the text ''each subsequent February 15,'' and adding in its place the text ''February 15, 2021,'', and removing the second period and adding in its place the text ''and recorded under § 97.921.'';
■ c. In paragraph (a)(2), removing the period and adding in its place the text ''and recorded under § 97.921.'';
■ d. In paragraph (a)(3)(ii)(A), removing the text ''paragraph (b)'' and adding in its place the text ''paragraph (d)'';
■ e. In paragraph (a)(3)(ii)(B), removing the text ''paragraph (b)'' wherever it appears and adding in its place the text ''paragraph (d)'', and adding a new sentence between the existing first and second sentences;
■ f. In paragraph (a)(3)(iii), removing the text ''paragraph (b)'' and adding in its place the text ''paragraph (d)'';
■ g. Redesignating paragraphs (a)(4) and (b) as paragraphs (c) and (d) and adding a new paragraph (b); and
■ h. Revising newly redesignated paragraph (d).

The addition and revision read as follows:

§ 97.912 Texas SO_2 Trading Program Supplemental Allowance Pool.

(a) * * *

(3) * * *

(ii) * * *

(B) * * * The Administrator will adjust the sources' allocations up or down by one allowance, starting with the largest allocation and continuing in descending order, as necessary to cause the sum of the sources' allocations to equal the total number of allowances in the Supplemental Allowance Pool available for allocation under paragraph (d) of this section that remain after any allocation under paragraph (a)(3)(i) of this section. * * *

* * * * *

(b) For each control period in 2021 and thereafter, the Administrator will allocate Texas SO_2 Trading Program allowances from the Texas SO_2 Trading Program Supplemental Allowance Pool as follows:

(1) For each control period, the Administrator will assign each Texas SO_2 Trading Program unit to an affiliated ownership group reflecting the unit's ownership as of December 31 of the control period. The affiliated ownership group assignments for each control period will be as shown in § 97.911(a)(1) except that the Administrator will revise the assignments, based on the information required to be submitted in accordance with § 97.915(c) and any other information available to the Administrator, as necessary to reflect any ownership transfer resulting in a 50% or greater ownership share of a unit being held by a new owner that the Administrator determines is not affiliated with the previous holder of a 50% or greater ownership share of the unit.

(2) No later than February 15, 2022 and each subsequent February 15, the Administrator will review all the quarterly SO_2 emissions reports provided under § 97.934(d) for each Texas SO_2 Trading Program unit for the previous control period. The Administrator will identify each affiliated ownership group of Texas SO_2 Trading Program units as of December 31 of such control period for which the total amount of emissions reported for the units in the group for that control period exceeds the total amount of allowances allocated to the units in the group for that control period under § 97.911 and recorded under § 97.921.

(3) For each affiliated ownership group of Texas SO_2 Trading Program units identified under paragraph (b)(2) of this section, the Administrator will calculate the amount by which the total amount of reported emissions for that control period exceeds the total amount of allowances allocated for that control period under § 97.911 and recorded under § 97.921.

(4)(i) The Administrator will allocate and record allowances from the Supplemental Allowance Pool as follows:

(A) If the total for all such affiliated ownership groups of the amounts calculated under paragraph (b)(3) of this section is less than or equal to the total number of allowances in the Supplemental Allowance Pool available for allocation under paragraph (d) of this section, then each such group's allocation of allowances from the Supplemental Allowance Pool shall equal to the amount calculated for the group under paragraph (b)(3) of this section.

(B) If the total for all such affiliated ownership groups of the amounts calculated under paragraph (b)(3) of this section is greater than the total number of allowances in the Supplemental Allowance Pool available for allocation under paragraph (d) of this section, then the Administrator will calculate each such group's allocation of allowances from the Supplemental Allowance Pool by dividing the amount calculated under paragraph (b)(3) of this section for the group by the sum of the amounts calculated under paragraph (b)(3) of this section for all such groups, then multiplying by the number of allowances in the Supplemental Allowance Pool available for allocation under paragraph (d) of this section and rounding to the nearest allowance. The Administrator will adjust the groups' allocations up or down by one allowance, starting with the largest allocation and continuing in descending order, as necessary to cause the sum of the groups' allocations to equal the total number of allowances in the Supplemental Allowance Pool available for allocation under paragraph (d) of this section.

(C) When an affiliated ownership group receives an allocation of allowances under paragraph (b)(4)(i)(A) or (B) of this section, each source in the group whose emissions during the control period for which allowances are being allocated exceed the amount of allowances allocated to the source under § 97.911 and recorded under § 97.921 will receive a share of the group's allocation. The Administrator will compute each such source's share by dividing the amount of the source's emissions during the control period exceeding the source's allocation under § 97.911 by the sum for all such sources of the amounts of the sources' emissions during the control period exceeding the sources' allocations under § 97.911, then multiplying by the group's allocation under paragraph (b)(4)(i)(A) or (B) of this section and rounding to the nearest allowance. The Administrator will adjust the sources' allocations up or down by one allowance, starting with the largest allocation and continuing in descending order, as necessary to cause the sum of the sources' allocations to equal the group's allocation. The Administrator will then record the calculated allocations of allowances in the applicable sources' compliance accounts.

(ii) Any unallocated allowances remaining in the Supplemental Allowance Pool after the allocations determined under paragraph (b)(4)(i) of this section will be maintained in the Supplemental Allowance Pool. These allowances will be available for allocation by the Administrator in subsequent control periods to the extent consistent with paragraph (d) of this section.

* * * * *

(d) The total amount of allowances in the Supplemental Allowance Pool available for allocation for a control period is equal to the sum of the Supplemental Allowance Pool budget under § 97.910(a)(2), any allowances from retired units pursuant to § 97.911(a)(2) and from corrections pursuant to § 97.911(c)(5), and any allowances maintained in the Supplemental Allowance Pool pursuant to paragraph (a)(3)(iii) or (b)(4)(ii) of this

section, provided that if the number of allowances in the Supplemental Allowance Pool exceeds the applicable limit for the control period under paragraph (d)(1) or (d)(2) of this section, then the Administrator may only allocate allowances up to such applicable limit.

(1) For the control periods in 2019 and 2020, the total amount of allowances allocated from the Supplemental Allowance Pool for a control period may not exceed by more than 44,711 tons the sum of the Supplemental Allowance Pool budget under § 97.910(a)(2) and any portion of the Texas SO_2 Trading Program budget under § 97.910(a)(1) not otherwise allocated for that control period under § 97.911(a)(1).

(2) For each control period in 2021 and thereafter, the total amount of allowances allocated from the Supplemental Allowance Pool for a control period may not exceed the sum of the variability limit under § 97.910(b) and any portion of the Texas SO_2 Trading Program budget under § 97.910(a)(1) not otherwise allocated for that control period under § 97.911(a)(1).

■ 8. Amend § 97.913 by revising paragraph (c) to read as follows:

§ 97.913 Authorization of designated representative and alternate designated representative.

* * * * *

(c) Except in this section, § 97.902, and §§ 97.914 through 97.918, whenever the term ''designated representative'' (as distinguished from the term ''common designated representative'') is used in this subpart, the term shall be construed to include the designated representative or any alternate designated representative.

§ 97.915 [Amended]

■ 9. Amend § 97.915 paragraph (d) introductory text and paragraph (d)(1) by removing the text ''(see § 97.904(b))''.

■ 10. Amend § 97.920 by:

■ a. Revising the section heading;

■ b. Redesignating paragraphs (b) through (d) as paragraphs (c) through (e) and adding a new paragraph (b);

■ c. In newly redesignated paragraph (c)(2)(i) introductory text, removing the text ''paragraph (b)(1)'' and adding in its place the text ''paragraph (c)(1)'';

■ d. In newly redesignated paragraph (c)(2)(ii), removing the text ''paragraph (b)(5)'' and adding in its place the text ''paragraph (c)(5)'';

■ e. In newly redesignated paragraphs (c)(3)(i) and (ii), removing the text ''paragraph (b)(1)'' and adding in its place the text ''paragraph (c)(1)'';

■ f. In newly redesignated paragraph (c)(4)(i), removing the text ''paragraph (b)(1)'' wherever it appears and adding in its place the text ''paragraph (c)(1)'';

■ g. In newly redesignated paragraph (c)(4)(ii), removing the text ''paragraph (b)(4)(i)'' and adding in its place the text ''paragraph (c)(4)(i)'';

■ h. In newly redesignated paragraph (c)(5)(iii) introductory text and paragraph (c)(5)(iii)(C), removing the text ''paragraph (b)(5)(i)'' and adding in its place the text ''paragraph (c)(5)(i)'';

■ i. In newly redesignated paragraph (c)(5)(iii)(D), removing the text ''97.920(b)(5)(iv)'' and adding in its place the text ''97.920(c)(5)(iv)'';

■ j. In newly redesignated paragraph (c)(5)(iii)(E), removing the text ''97.920(b)(5)(iv),'' and adding in its place the text ''97.920(c)(5)(iv),'', and removing the text ''97.920(b)(5)'' and adding in its place the text ''97.920(c)(5)'';

■ k. In newly redesignated paragraph (c)(5)(iv), removing the text ''paragraph (b)(5)(iii)'' and adding in its place the text ''paragraph (c)(5)(iii)'';

■ l. In newly redesignated paragraph (c)(5)(v), removing the text ''paragraph (b)(5)(iii)(D)'' and adding in its place the text ''paragraph (c)(5)(iii)(D)'', and removing the text ''paragraph (b)(5)(iv)'' and adding in its place the text ''paragraph (c)(5)(iv)'';

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

■ n. In newly redesignated paragraph (e), removing the text ''paragraphs (b)(2)(ii) and (b)(5)'' and adding in its place the text ''paragraphs (c)(2)(ii) and (c)(5)''.

The revision and addition read as follows:

§ 97.920 Establishment of compliance accounts, assurance accounts, and general accounts.

* * * * *

(b) *Assurance accounts.* The Administrator will establish assurance accounts for certain owners and operators and States in accordance with § 97.925(b)(3).

* * * * *

■ 11. Amend § 97.921 by:

■ a. In paragraph (a), removing the second sentence;

■ b. Revising paragraphs (b) and (c);

■ c. Removing and reserving paragraph (d); and

■ d. Adding paragraph (f).

The revisions and addition read as follows:

§ 97.921 Recordation of Texas SO_2 Trading Program allowance allocations.

* * * * *

(b) By July 1, 2019, the Administrator will record in each Texas SO_2 Trading Program source's compliance account the Texas SO_2 Trading Program allowances allocated to the Texas SO_2 Trading Program units at the source in accordance with § 97.911(a) for the control period in the fourth year after the year of the applicable recordation deadline under this paragraph, unless provided otherwise in the Administrator's approval of a SIP revision replacing the provisions of this subpart.

(c) By February 15, 2020, and February 15 of each year thereafter, the Administrator will record in each Texas SO_2 Trading Program source's compliance account the allowances allocated from the Texas SO_2 Trading Program Supplemental Allowance Pool in accordance with § 97.912 for the control period in the year of the applicable recordation deadline under this paragraph, unless provided otherwise in the Administrator's approval of a SIP revision replacing the provisions of this subpart.

* * * * *

(f) Notwithstanding paragraphs (a) and (b) of this section, with respect to the Texas SO_2 Trading Program allowances allocated to Newman Unit **5 in accordance with § 97.911(a) for the control periods in 2019, 2020, 2021, 2022, 2023, and 2024, the Administrator will record the allowances in the source's compliance account by December 31, 2020, unless provided otherwise in the Administrator's approval of a SIP revision replacing the provisions of this subpart.

■ 12. Add § 97.925 to read as follows:

§ 97.925 Compliance with Texas SO_2 Trading Program assurance provisions.

(a) *Availability for deduction.* Texas SO_2 Trading Program allowances are available to be deducted for compliance with the Texas SO_2 Trading Program assurance provisions for a control period in a given year by the owners and operators of a group of one or more Texas SO_2 Trading Program sources and units only if the Texas SO_2 Trading Program allowances:

(1) Were allocated for a control period in a prior year or the control period in the given year or in the immediately following year; and

(2) Are held in the assurance account, established by the Administrator for such owners and operators of such group of Texas SO_2 Trading Program sources and units under paragraph (b)(3) of this section, as of the deadline established in paragraph (b)(4) of this section.

(b) *Deductions for compliance.* The Administrator will deduct Texas SO_2 Trading Program allowances available under paragraph (a) of this section for compliance with the Texas SO_2 Trading Program assurance provisions for a control period in a given year in accordance with the following procedures:

(1) By June 1, 2022 and June 1 of each year thereafter, the Administrator will:

(i) Calculate the total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources during the control period in the year before the year of this calculation deadline and the amount, if any, by which such total SO_2 emissions exceed the State assurance level as described in § 97.906(c)(2)(iii).

(ii) [Reserved]

(2) If the calculations under paragraph (b)(1)(i) of this section indicate that the total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources during such control period exceed the State assurance level as described in § 97.906(c)(2)(iii):

(i) [Reserved]

(ii) By August 1 immediately after the deadline for the calculations under paragraph (b)(1)(i) of this section, the Administrator will calculate, for such control period and each common designated representative for such control period for a group of one or more Texas SO_2 Trading Program sources and units, the common designated representative's share of the total SO_2 emissions from all Texas SO_2 Trading Program units at Texas SO_2 Trading Program sources, the common designated representative's assurance level, and the amount (if any) of Texas SO_2 Trading Program allowances that the owners and operators of such group of sources and units must hold in accordance with the calculation formula in § 97.906(c)(2)(i). By each such August 1, the Administrator will promulgate a notice of data availability of the results of the calculations under this paragraph and paragraph (b)(1)(i) of this section, including separate calculations of the SO_2 emissions from each Texas SO_2 Trading Program source.

(iii) The Administrator will provide an opportunity for submission of objections to the calculations referenced by the notice of data availability required in paragraph (b)(2)(ii) of this section.

(A) Objections shall be submitted by the deadline specified in such notice and shall be limited to addressing whether the calculations referenced in the notice required under paragraph (b)(2)(ii) of this section are in accordance with § 97.906(c)(2)(iii), §§ 97.906(b) and 97.930 through 97.935, the definitions of ''common designated representative'', ''common designated representative's assurance level'', and ''common designated representative's share'' in § 97.902, and the calculation formula in § 97.906(c)(2)(i).

(B) The Administrator will adjust the calculations to the extent necessary to ensure that they are in accordance with the provisions referenced in paragraph (b)(2)(iii)(A) of this section. By October 1 immediately after the promulgation of such notice, the Administrator will promulgate a notice of data availability of the calculations incorporating any adjustments that the Administrator determines to be necessary and the reasons for accepting or rejecting any objections submitted in accordance with paragraph (b)(2)(iii)(A) of this section.

(3) The Administrator will establish one assurance account for each set of owners and operators referenced, in the notice of data availability required under paragraph (b)(2)(iii)(B) of this section, as all of the owners and operators of a group of Texas SO_2 Trading Program sources and units having a common designated representative for such control period and as being required to hold Texas SO_2 Trading Program allowances.

(4)(i) As of midnight of November 1 immediately after the promulgation of each notice of data availability required in paragraph (b)(2)(iii)(B) of this section, the owners and operators described in paragraph (b)(3) of this section shall hold in the assurance account established for them and for the appropriate Texas SO_2 Trading Program sources and Texas SO_2 Trading Program units under paragraph (b)(3) of this section a total amount of Texas SO_2 Trading Program allowances, available for deduction under paragraph (a) of this section, equal to the amount such owners and operators are required to hold with regard to such sources and units as calculated by the Administrator and referenced in such notice.

(ii) Notwithstanding the allowance-holding deadline specified in paragraph (b)(4)(i) of this section, if November 1 is not a business day, then such allowance-holding deadline shall be midnight of the first business day thereafter.

(5) After November 1 (or the date described in paragraph (b)(4)(ii) of this section) immediately after the promulgation of each notice of data availability required in paragraph (b)(2)(iii)(B) of this section and after the recordation, in accordance with § 97.923, of Texas SO_2 Trading Program allowance transfers submitted by midnight of such date, the Administrator will determine whether the owners and operators described in paragraph (b)(3) of this section hold, in the assurance account for the appropriate Texas SO_2 Trading Program sources and Texas SO_2 Trading Program units established under paragraph (b)(3) of this section, the amount of Texas SO_2 Trading Program allowances available under paragraph (a) of this section that the owners and operators are required to hold with regard to such sources and units as calculated by the Administrator and referenced in the notice required in paragraph (b)(2)(iii)(B) of this section.

(6) Notwithstanding any other provision of this subpart and any revision, made by or submitted to the Administrator after the promulgation of the notice of data availability required in paragraph (b)(2)(iii)(B) of this section for a control period in a given year, of any data used in making the calculations referenced in such notice, the amounts of Texas SO_2 Trading Program allowances that the owners and operators are required to hold in accordance with § 97.906(c)(2)(i) for such control period shall continue to be such amounts as calculated by the Administrator and referenced in such notice required in paragraph (b)(2)(iii)(B) of this section, except as follows:

(i) If any such data are revised by the Administrator as a result of a decision in or settlement of litigation concerning such data on appeal under part 78 of this chapter of such notice, or on appeal under section 307 of the Clean Air Act of a decision rendered under part 78 of this chapter on appeal of such notice, then the Administrator will use the data as so revised to recalculate the amounts of Texas SO_2 Trading Program allowances that owners and operators are required to hold in accordance with the calculation formula in § 97.906(c)(2)(i) for such control period with regard to the Texas SO_2 Trading Program sources and Texas SO_2 Trading Program units involved, provided that such litigation under part 78 of this chapter, or the proceeding under part 78 of this chapter that resulted in the decision appealed in such litigation under section 307 of the Clean Air Act, was initiated no later than 30 days after promulgation of such notice required in paragraph (b)(2)(iii)(B) of this section.

(ii) [Reserved]

(iii) If the revised data are used to recalculate, in accordance with paragraph (b)(6)(i) of this section, the amount of Texas SO_2 Trading Program allowances that the owners and operators are required to hold for such control period with regard to the Texas

SO_2 Trading Program sources and Texas SO_2 Trading Program units involved—

(A) Where the amount of Texas SO_2 Trading Program allowances that the owners and operators are required to hold increases as a result of the use of all such revised data, the Administrator will establish a new, reasonable deadline on which the owners and operators shall hold the additional amount of Texas SO_2 Trading Program allowances in the assurance account established by the Administrator for the appropriate Texas SO_2 Trading Program sources and Texas SO_2 Trading Program units under paragraph (b)(3) of this section. The owners' and operators' failure to hold such additional amount, as required, before the new deadline shall not be a violation of the Clean Air Act. The owners' and operators' failure to hold such additional amount, as required, as of the new deadline shall be a violation of the Clean Air Act. Each Texas SO_2 Trading Program allowance that the owners and operators fail to hold as required as of the new deadline, and each day in such control period, shall be a separate violation of the Clean Air Act.

(B) For the owners and operators for which the amount of Texas SO_2 Trading Program allowances required to be held decreases as a result of the use of all such revised data, the Administrator will record, in all accounts from which Texas SO_2 Trading Program allowances were transferred by such owners and operators for such control period to the assurance account established by the Administrator for the appropriate Texas SO_2 Trading Program sources and Texas SO_2 Trading Program units under paragraph (b)(3) of this section, a total amount of the Texas SO_2 Trading Program allowances held in such assurance account equal to the amount of the decrease. If Texas SO_2 Trading Program allowances were transferred to such assurance account from more than one account, the amount of Texas SO_2 Trading Program allowances recorded in each such transferor account will be in proportion to the percentage of the total amount of Texas SO_2 Trading Program allowances transferred to such assurance account for such control period from such transferor account.

(C) Each Texas SO_2 Trading Program allowance held under paragraph (b)(6)(iii)(A) of this section as a result of recalculation of requirements under the Texas SO_2 Trading Program assurance provisions for such control period must be a Texas SO_2 Trading Program allowance allocated for a control period in a year before or the year immediately following, or in the same year as, the year of such control period.

§ 97.926 [Amended]

■ 13. Amend § 97.926 paragraph (b) by adding the text ''§ 97.925,''after the text ''§ 97.924,''.

§ 97.928 [Amended]

■ 14. Amend § 97.928 paragraph (b) by removing the text ''a compliance account,'' and adding in its place the text ''a compliance account or an assurance account,''.

§ 97.930 [Amended]

■ 15. Amend § 97.930 by:

■ a. In paragraph (b) introductory text, removing the colon and adding in its place the text ''January 1, 2019.'';

■ b. Removing and reserving paragraphs (b)(1) and (2); and

■ c. In paragraph (b)(3) introductory text, removing the text ''the applicable deadline under paragraph (b)(1) or (2) of this section'' and adding in its place the text ''January 1, 2019''.

§ 97.931 [Amended]

■ 16. In § 97.931 amend paragraph (d)(3) introductory text by removing in the last sentence the word ''with'' after the text ''is replaced by''.

§ 97.934 [Amended]

■ 17. Amend § 97.934 by:

■ a. In paragraph (d)(1) introductory text, removing the text ''the later of:'' and adding in its place the text ''the calendar quarter covering January 1, 2019 through March 31, 2019.''; and

■ b. Removing paragraphs (d)(1)(i) and (ii).

[FR Doc. 2020–14408 Filed 8–11–20; 8:45 am]

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Part V

The President

Memorandum of August 7, 2020—Extension of the Use of the National Guard To Respond to COVID–19 and To Facilitate Economic Recovery
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Federal Register
Vol. 85, No. 156
Wednesday, August 12, 2020

Presidential Documents

Title 3—

The President

Memorandum of August 7, 2020

Extension of the Use of the National Guard To Respond to COVID–19 and To Facilitate Economic Recovery

Memorandum for the Secretary of Defense [and] the Secretary of Homeland Security

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the ''Stafford Act''), and section 502 of title 32, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It continues to be the policy of the United States to foster close cooperation and mutual assistance between the Federal Government and the States and territories in the battle against the threat posed by the spread of COVID–19, especially as the United States transitions to a period of increased economic activity and recovery in those areas of the Nation where the threat posed by COVID–19 has been sufficiently mitigated. To date, activated National Guard forces around the country have provided critical support to Governors as the Governors work to address the needs of those populations within their respective States and territories especially vulnerable to the effects of COVID–19, including those in nursing homes, assisted living facilities, and other long-term care or congregate settings. Additionally, States and territories will need assistance in fighting COVID–19 hot spots as they emerge. Therefore, to continue to provide maximum support to States and territories as they make decisions about the responses required to address local conditions in their respective jurisdictions with respect to combatting the threat posed by COVID–19 and, where appropriate, facilitating their economic recovery, I am taking the actions set forth in sections 2 and 3 of this memorandum:

Sec. 2. *Additional Twenty-Five Percent Federal Cost Share.* To maximize assistance to the Governor of the State of Arizona to facilitate Federal support with respect to the use of National Guard units under State control, I am directing the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security to fund an additional 25 percent of the emergency assistance activities associated with preventing, mitigating, and responding to the threat to public health and safety posed by the virus that this State undertakes using its National Guard forces, as authorized by sections 403 (42 U.S.C. 5170b) and 503 (42 U.S.C. 5193) of the Stafford Act. This, in addition to the 75 percent Federal cost share established in my prior memorandum dated August 3, 2020, titled ''Extension of the Use of the National Guard to Respond to COVID–19 and to Facilitate Economic Recovery,'' shall provide the State of Arizona with 100 percent Federal cost share.

Sec. 3. *Additional Twenty-Five Percent Federal Cost Share Termination.* The additional 25 percent Federal cost share for the State's use of National Guard forces for the State of Arizona shall extend to, and shall be available for orders of any length authorizing duty through September 30, 2020. Such orders include duty necessary to comply with health protection protocols recommended by the Centers for Disease Control and Prevention of the Department of Health and Human Services or other health protection measures agreed to by the Department of Defense and FEMA.

Sec. 4. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

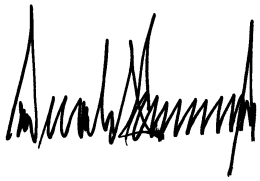
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Defense is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 7, 2020

[FR Doc. 2020–17784
Filed 8–11–20; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Memorandum of August 7, 2020

Extension of the Use of the National Guard To Respond to COVID–19 and To Facilitate Economic Recovery

Memorandum for the Secretary of Defense [and] the Secretary of Homeland Security

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the ''Stafford Act''), and section 502 of title 32, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It continues to be the policy of the United States to foster close cooperation and mutual assistance between the Federal Government and the States and territories in the battle against the threat posed by the spread of COVID–19, especially as the United States transitions to a period of increased economic activity and recovery in those areas of the Nation where the threat posed by COVID–19 has been sufficiently mitigated. To date, activated National Guard forces around the country have provided critical support to Governors as the Governors work to address the needs of those populations within their respective States and territories especially vulnerable to the effects of COVID–19, including those in nursing homes, assisted living facilities, and other long-term care or congregate settings. Additionally, States and territories will need assistance in fighting COVID–19 hot spots as they emerge. Therefore, to continue to provide maximum support to States and territories as they make decisions about the responses required to address local conditions in their respective jurisdictions with respect to combatting the threat posed by COVID–19 and, where appropriate, facilitating their economic recovery, I am taking the actions set forth in sections 2 and 3 of this memorandum:

Sec. 2. *Additional Twenty-Five Percent Federal Cost Share.* To maximize assistance to the Governor of the State of California to facilitate Federal support with respect to the use of National Guard units under State control, I am directing the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security to fund an additional 25 percent of the emergency assistance activities associated with preventing, mitigating, and responding to the threat to public health and safety posed by the virus that this State undertakes using its National Guard forces, as authorized by sections 403 (42 U.S.C. 5170b) and 503 (42 U.S.C. 5193) of the Stafford Act. This, in addition to the 75 percent Federal cost share established in my prior memorandum dated August 3, 2020, titled ''Extension of the Use of the National Guard to Respond to COVID–19 and to Facilitate Economic Recovery,'' shall provide the State of California with 100 percent Federal cost share.

Sec. 3. *Additional Twenty-Five Percent Federal Cost Share Termination.* The additional 25 percent Federal cost share for the State's use of National Guard forces for the State of California shall extend to, and shall be available for orders of any length authorizing duty through September 30, 2020. Such orders include duty necessary to comply with health protection protocols recommended by the Centers for Disease Control and Prevention of the Department of Health and Human Services or other health protection measures agreed to by the Department of Defense and FEMA.

Sec. 4. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

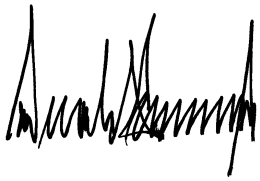
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Defense is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 7, 2020

[FR Doc. 2020–17786
Filed 8–11–20; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Memorandum of August 7, 2020

Extension of the Use of the National Guard To Respond to COVID–19 and To Facilitate Economic Recovery

Memorandum for the Secretary of Defense [and] the Secretary of Homeland Security

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the ''Stafford Act''), and section 502 of title 32, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It continues to be the policy of the United States to foster close cooperation and mutual assistance between the Federal Government and the States and territories in the battle against the threat posed by the spread of COVID–19, especially as the United States transitions to a period of increased economic activity and recovery in those areas of the Nation where the threat posed by COVID–19 has been sufficiently mitigated. To date, activated National Guard forces around the country have provided critical support to Governors as the Governors work to address the needs of those populations within their respective States and territories especially vulnerable to the effects of COVID–19, including those in nursing homes, assisted living facilities, and other long-term care or congregate settings. Additionally, States and territories will need assistance in fighting COVID–19 hot spots as they emerge. Therefore, to continue to provide maximum support to States and territories as they make decisions about the responses required to address local conditions in their respective jurisdictions with respect to combatting the threat posed by COVID–19 and, where appropriate, facilitating their economic recovery, I am taking the actions set forth in sections 2 and 3 of this memorandum:

Sec. 2. *Additional Twenty-Five Percent Federal Cost Share.* To maximize assistance to the Governor of the State of Connecticut to facilitate Federal support with respect to the use of National Guard units under State control, I am directing the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security to fund an additional 25 percent of the emergency assistance activities associated with preventing, mitigating, and responding to the threat to public health and safety posed by the virus that this State undertakes using its National Guard forces, as authorized by sections 403 (42 U.S.C. 5170b) and 503 (42 U.S.C. 5193) of the Stafford Act. This, in addition to the 75 percent Federal cost share established in my prior memorandum dated August 3, 2020, titled ''Extension of the Use of the National Guard to Respond to COVID–19 and to Facilitate Economic Recovery,'' shall provide the State of Connecticut with 100 percent Federal cost share.

Sec. 3. *Additional Twenty-Five Percent Federal Cost Share Termination.* The additional 25 percent Federal cost share for the State's use of National Guard forces for the State of Connecticut shall extend to, and shall be available for orders of any length authorizing duty through September 30, 2020. Such orders include duty necessary to comply with health protection protocols recommended by the Centers for Disease Control and Prevention of the Department of Health and Human Services or other health protection measures agreed to by the Department of Defense and FEMA.

Sec. 4. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

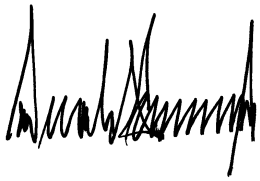
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Defense is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 7, 2020

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